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**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION**

*IN RE NATERA PRENATAL TESTING
LITIGATION*

Case No. 4:22-cv-00985-JST

Hon. Jon S. Tigar

**FIRST AMENDED CONSOLIDATED
CLASS ACTION COMPLAINT**

JURY TRIAL DEMANDED

1 **I. OVERVIEW OF THE CASE**

2 1. During a pregnancy, prenatal testing is used to determine whether the fetus presents with
3 chromosomal disorders, such as Down syndrome and other serious conditions that can result in a
4 shortened lifespan, severe medical complications, and intellectual disability. Expectant mothers and
5 their doctors rely on the results of prenatal testing to make potentially life-altering decisions, including
6 whether to continue with the pregnancy. In the past decade, purported advances in noninvasive prenatal
7 testing or NIPT have allowed companies to offer tests that they claim can detect chromosomal
8 abnormalities earlier in pregnancy, and without posing risk to the fetus, simply by testing a sample of
9 the expectant mother's blood.

10 2. Defendant Natera, Inc. markets and sells NIPT tests that screen pregnant women for
11 various chromosomal and genetic conditions affecting a baby's health. Natera markets its NIPT tests as
12 the most reliable non-invasive method of screening for genetic conditions, advertising their accuracy.

13 3. But, while NIPT testing is generally effective at screening for Down syndrome, Natera's
14 NIPT tests return false positive test results for some rare genetic conditions 85 percent of the time or
15 more—sometimes up to 98 percent. What is more, numerous studies have found that the positive
16 predictive value ("PPV")—the likelihood that a positive result is in fact correct—for Natera's NIPT tests
17 is unacceptably low—as low as 18%—for numerous genetic conditions.

18 4. A false positive on a prenatal test can wreak severe harm upon expecting parents.
19 Besides causing unnecessary anxiety, stress, and anguish about the health of the baby, a false positive
20 NIPT leads many pregnant women to undergo invasive and expensive diagnostic testing, genetic
21 counseling, and consultations with doctors specializing in high-risk pregnancies. In addition, because
22 NIPT typically is performed relatively early in the pregnancy, diagnostic testing is not always
23 immediately available to confirm the test results. In some states, diagnostic testing may not become
24 available until after the period when a pregnancy may be legally terminated, meaning some expectant
25 parents have only the results of the NIPT testing to rely on in making the extremely difficult, life-
26 altering decision of whether to proceed with a pregnancy. Even if it is available, follow-up testing is
27 highly invasive and carries a risk of miscarriage. According to a *New York Times* investigation, some
28 expectant mothers have terminated viable pregnancies based upon a false positive NIPT test result.

1 5. On April 19, 2022, citing reports that “patients and health care providers have made
2 critical health care decisions based on results from these screening tests alone,” including “ending
3 pregnancies,” the U.S. Food and Drug Administration (“FDA”) issued a warning to consumers that “the
4 results of these tests may not accurately reflect whether your fetus has a genetic abnormality.”¹

5 6. Natera has known for years yet failed to disclose that its NIPT tests are susceptible to a
6 high rate of false positives and are of little use when screening for certain rare genetic disorders. Even
7 today, Natera continues to promote its NIPT test as a reliable detector of rare abnormalities. The
8 message that patients receive as a consequence of Natera’s marketing is that its NIPT test produces
9 fewer false positives than competing tests. Meanwhile Natera suppresses and fails to reveal the extent to
10 which pregnant women and their doctors may be induced to make health decisions based on inaccurate
11 test results.

12 7. Natera processes more than 400,000 NIPT tests each year, meaning it tests about one in
13 ten pregnant women in the United States. Each patient understands that the results of the test will be
14 generally reliable—which is the whole point of doing the test. Considering the numerous flaws with the
15 test that have come to light, users of Natera’s NIPT test have not received what they paid for, and
16 Plaintiffs and many other pregnant women have been subjected to added medical costs, as well as
17 unnecessary stress and anxiety, due to a false positive indication of a rare disorder.

18 **II. JURISDICTION AND VENUE**

19 8. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C.
20 § 1332 of the Class Action Fairness Act of 2005 because: (i) there are 100 or more class members, (ii)
21 the aggregate amount in controversy exceeds \$5,000,000 exclusive of costs and interest, and (iii) there is
22 minimal diversity because at least one plaintiff and one defendant are citizens of different states. This
23 Court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367.

24 9. This Court has general personal jurisdiction over Defendant because its principal place of
25 business is in this District. The Court also has specific personal jurisdiction over Defendant because it
26 engages in substantial business in this District and Plaintiffs’ claims arise out of or relate to Natera’s
27

28 ¹ <https://www.fda.gov/medical-devices/safety-communications/genetic-non-invasive-prenatal-screening-tests-may-have-false-results-fda-safety-communication>.

forum-related activities.

10. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 because Natera is headquartered and regularly transacts business in this district, is subject to general personal jurisdiction in this district, and therefore is deemed to be a citizen of this district. Additionally, Natera received substantial revenue and profits from its sales of NIPT tests in this district. As such, a substantial part of the events and/or omissions giving rise to the claims at issue occurred, in part, in this District.

III. INTRADISTRICT ASSIGNMENT

11. Assignment to the San Francisco or Oakland Division is appropriate under Local Rules 3-2(c) and (d) because a substantial part of the events or omissions giving rise to Plaintiffs' claims occurred in San Mateo County.

IV. PARTIES

12. Plaintiff Lisa Cassinis was, at all times relevant to the claims in this action, a citizen and resident of Los Angeles, California.

13. Plaintiff Sara Martinez is a citizen and resident of South Pasadena, California.

14. Plaintiff Amanda Law was, at all times relevant to the claims in this action, a citizen and resident of Fort Lauderdale, Florida.

15. Plaintiff Lillian Delaurie is a citizen and resident of Glendale Heights, Illinois.

16. Plaintiff Laura Ashley Heryla is a citizen and resident of Nottingham, Maryland.

17. Plaintiff Yelena Kreynstein is a citizen and resident of Morganville, New Jersey.

18. Plaintiff Chelsey Stephens is a citizen and resident of Brooklyn, New York.

19. Plaintiff Amanda Davis is a citizen and resident of Youngstown, Ohio.

20. Defendant Natera, Inc. is a Delaware corporation with its principal place of business at 201 Industrial Rd., Suite 410, San Carlos, California 94070.

V. FACTUAL BACKGROUND

A. Prenatal Testing

21. Prenatal testing is used to assess a pregnant patient's risk of carrying a child with chromosomal disorders that can affect the baby's health. When tests provide accurate information, prenatal genetic testing provides valuable information to pregnant patients about the health of their

1 unborn child. The genetic conditions these tests are directed towards can make a pregnancy non-viable
 2 or have serious impacts on the health of a surviving newborn, such as structural anomalies, intellectual
 3 disabilities, and a shortened lifespan. For example, DiGeorge syndrome is associated with heart defects
 4 and intellectual disability, and Patau syndrome is “a condition that babies often do not survive beyond a
 5 week.”²

6 22. A pregnant patient whose child has one of these conditions must confront serious
 7 questions about risks in continuing the pregnancy, the viability of the pregnancy, and the prognosis and
 8 quality of life for any surviving newborn. Some patients choose to terminate a pregnancy that has
 9 chromosomal abnormalities. One United Kingdom study in 2017 found that 63% of U.K. women with
 10 high-risk NIPT results go on to terminate their pregnancies.³

11 23. Prenatal testing generally includes both diagnostic tests and the more recently developed
 12 screening tests. NIPT is a screening test that uses a sample of a pregnant patient’s blood (which
 13 includes DNA of the fetus) to screen for a number of genetic conditions caused by an abnormal number
 14 of chromosomes.⁴

15 24. Screening tests differ from diagnostic tests in several ways. Although diagnostic tests
 16 provide much more accurate results, they are highly invasive. For example, one common diagnostic
 17 test, amniocentesis, involves insertion of a needle through the abdominal wall into the uterus to extract
 18 amniotic fluid surrounding the fetus.⁵ Another diagnostic test, chorionic villus sampling, involves
 19 testing of a sample of the placenta that is removed through the cervix or abdomen.⁶ In addition to being
 20 physically invasive, these tests are also associated with risks, including a risk of miscarriage.⁷

21 25. In contrast, screening tests are not invasive, requiring only a blood sample, and can be
 22 performed at a much earlier stage in a pregnancy. Because different states impose different time
 23 restrictions on when a pregnancy can be terminated, NIPT—which can be done much sooner in the term

24
 25 ² <https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html>.

26 ³ M. Hill *et al.*, “Has Noninvasive Prenatal Testing Impacted Termination of Pregnancy and Live Birth
 Rates of Infants with Down Syndrome?,” *Prenatal Diagnosis* 37, No. 13 (2017): 1281-90.

27 ⁴ <https://www.acog.org/womens-health/infographics/cell-free-dna-prenatal-screening-test>.

28 ⁵ <https://my.clevelandclinic.org/health/treatments/4206-genetic-amniocentesis>.

⁶ <https://www.mayoclinic.org/tests-procedures/chorionic-villus-sampling/about/pac-20393533>.

⁷ <https://www.forbes.com/sites/ellenmatloff/2022/01/06/what-the-nytimes-got-wrong-on-prenatal-screening/?sh=94aebd037a76>.

1 than diagnostic testing—takes on additional importance. NIPT can be done as early as 9 or 10 weeks
2 into pregnancy.⁸ These key differences make screening tests important to pregnant patients.

3 26. But screening tests generally lack the higher accuracy of a diagnostic test. The PPV of
4 each test is the likelihood that a positive screening result is accurate—*i.e.*, that the test result is positive
5 *and* that the fetus actually has the tested-for condition.⁹

6 27. NIPT is reasonably accurate at identifying the most common conditions like Down
7 syndrome (approximately 1 in 700 live births).¹⁰

8 **B. The Increased Use of NIPT Testing**

9 28. Although historically only offered to patients considered to be high risk because of their
10 age or personal or family history, prenatal screening has expanded significantly in the last decade. NIPT
11 was developed and grew until the American College of Obstetricians and Gynecologists (“ACOG”)
12 changed its guidance in 2020 to recommend that all pregnant patients “be offered both screening and
13 diagnostic testing options.”¹¹ The ACOG’s guidance is that “[t]esting for chromosomal abnormalities
14 should be an informed patient choice based on provision of adequate and accurate information, and the
15 patient’s clinical context, accessible health care resources, values, interests, and goals.”¹²

16 29. “In just over a decade, the tests have gone from laboratory experiments to an industry
17 that serves more than a third of the pregnant women in America. The tests initially looked for Down
18 syndrome and worked very well.”¹³ But, as *The New York Times* reported, “as manufacturers tried to
19 outsell each other, they began offering additional screenings for increasingly rare conditions” such as
20 DiGeorge syndrome and 1p36 deletion.¹⁴

21 30. Adding screening tests for rarer conditions caused by genetic microdeletions—tiny
22 pieces of missing DNA at the sub-chromosomal level—has helped companies compete in the growing
23

24 ⁸ <https://www.natera.com/womens-health/panorama-nipt-prenatal-screening>);
25 <https://www.acog.org/womens-health/infographics/cell-free-dna-prenatal-screening-test>.

26 ⁹ <https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/10/screening-for-fetal-chromosomal-abnormalities>.

27 ¹⁰ *Id.*

28 ¹¹ *Id.*

¹² *Id.*

¹³ <https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html>.

¹⁴ *Id.*

1 market. As *The New York Times* reported, “[a]ll the screenings could run on the same blood draw, and
 2 doctors already order many tests during short prenatal care visits, meaning some probably thought little
 3 of tacking on a few more.”¹⁵ Despite no added burden on the patient or doctors for including these
 4 additional tests, the upside for testing companies was significant, increasing costs from an average of
 5 \$695 for the basic tests to \$1,349 for the expanded panel.

6 31. The market for prenatal testing was recently estimated to range from \$600 million and is
 7 growing rapidly, with the number of women taking these tests expected to double by 2025.¹⁶

8 32. Natera has become a leader of this expanding market. “Natera has performed more than
 9 two million screenings for Down syndrome since 2013. It went public in 2015, and the value of its
 10 stock has grown to \$8.8 billion.”¹⁷ Natera “said that in 2020 it performed more than 400,000 screenings
 11 for one microdeletion — the equivalent of testing roughly 10 percent of pregnant women in America.”¹⁸

12 33. The expanded panel of screening options has played a significant role in Natera’s
 13 growth, which it expects to continue. Natera’s chief executive, Steve Chapman, reportedly said at an
 14 investor conference last January, “This is a really significant moment for the microdeletions business.”¹⁹
 15 Natera’s “2020 revenues were \$391 million, and it projected its 2021 revenues to exceed \$615 million.
 16 But if more insurers begin paying for microdeletion tests, Mr. Chapman said, the potential is ‘enormous’
 17 — it could bring in up to another \$300 million every year.”²⁰

18 34. By the end of the third quarter of 2021, Chapman claimed in an earnings call that
 19 Natera’s market share in NIPT was up to 40%.²¹ In a July 2021 interview, he said Natera was “by far
 20 the market leader, testing roughly 25% of all pregnancies in the U.S. and growing rapidly.”²²

22 ¹⁵ *Id.*

23 ¹⁶ *Id.*

24 ¹⁷ *Id.*

25 ¹⁸ *Id.*

26 ¹⁹ *Id.*

27 ²⁰ *Id.*

28 ²¹ Natera, Inc. Q-4 earnings Call transcript, Nov. 4, 2021, *available at*
<https://www.fool.com/earnings/call-transcripts/2021/11/05/natera-inc-ntra-q3-2021-earnings-call-transcript/>.

²² Paul Moss, Steve Chapman of Natera: Five Things You Need to Create a Highly Successful Startup, *Authority Magazine*, July 7, 2021, *available at* <https://medium.com/authority-magazine/steve-chapman-of-natera-five-things-you-need-to-create-a-highly-successful-startup-5815f3621ace>.

C. Natera's Marketing of its NIPT Test

35. Natera advertises its NIPT test, "Panorama," as "the most reliable way of non-invasively assessing a baby's health" and claims that Panorama is "overall the most accurate NIPT commercially available in the United States."²³

36. When it launched in 2013, Natera touted Panorama as "a very reliable, yet safe noninvasive prenatal test" with "no false positives for all the syndromes tested."²⁴ Given its purportedly revolutionary nature, Natera "look[ed] forward to broadly extending the full benefits of Panorama's technology" in the future.²⁵ Shortly thereafter, in 2014, Natera announced that, in addition to screening for Down Syndrome, Trisomy 18, and Trisomy 13, the Panorama test would now screen for several microdeletion syndromes, including DiGeorge, Angelman, Cri-du-chat, and Prader-Willi syndromes.²⁶

37. As shown below, Natera's marketing—both to patients and to doctors—highlights the test's "greater accuracy," and characterizes it as the "most reliable way of non-invasively assessing a baby's health."²⁷

The only SNP-based NIPT delivers more insights and greater accuracy

Panorama is:

- the most rigorously validated NIPT
- the only NIPT that distinguishes mother's DNA from baby's DNA
- the approach that creates unique, clinically validated capabilities

Panorama evaluates SNPs— the 1% of our DNA that makes us different from one another

Diagram illustrating the SNP-based NIPT process, showing DNA sequences for Baby and Mother, highlighting a SNP (Single Nucleotide Polymorphism) where the sequences differ (e.g., A vs T, G vs C).

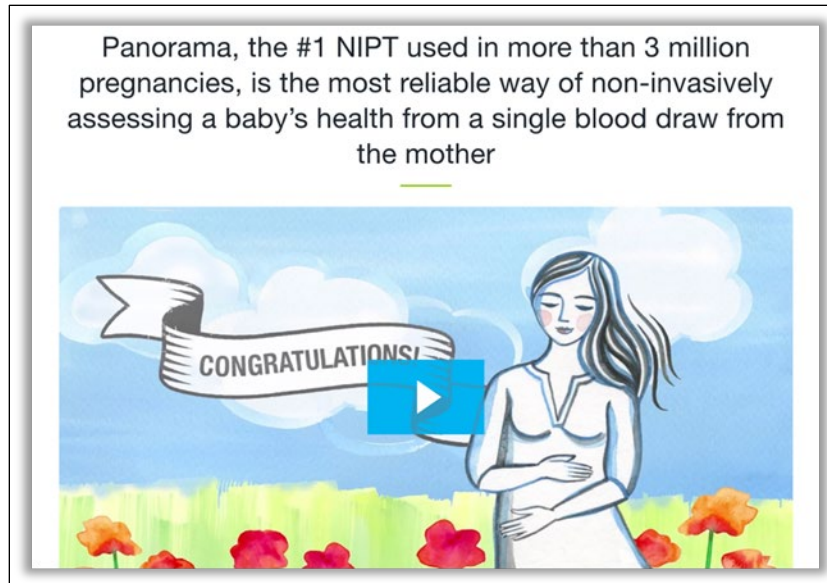
²³ Natera, Inc., 2020 10-K, Feb. 26, 2021 at 9, available at <https://investor.natera.com/sec-filings/sec-filing/10-k/0001558370-21-001907>.

²⁴ <https://investor.natera.com/news-releases/news-release-details/natera-launches-non-invasiveprenatal-test-panoramatm-best-class>.

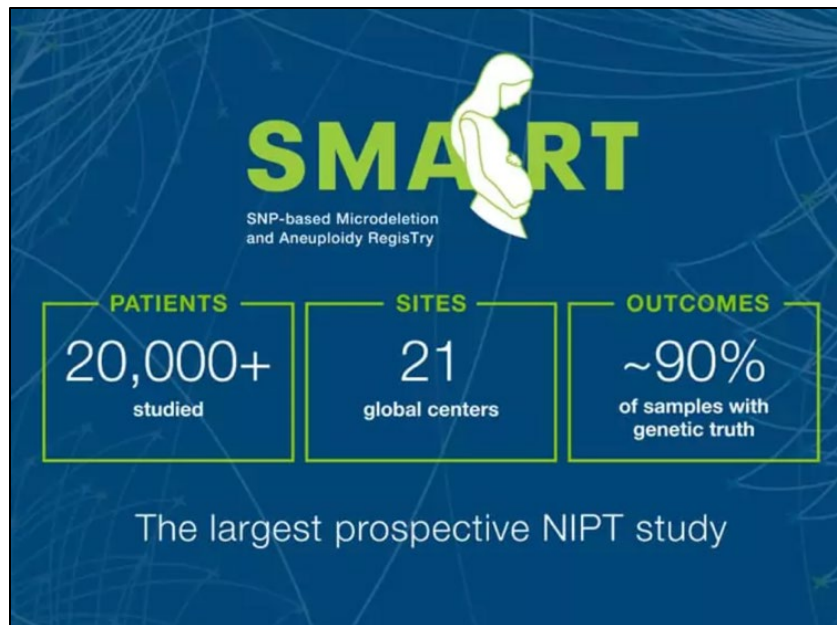
²⁵ *Id.*

²⁶ <https://www.natera.com/womens-health/panorama-nipt-prenatal-screening/>.

²⁷ <https://www.natera.com/womens-health/panorama-nipt-prenatal-screening/>.



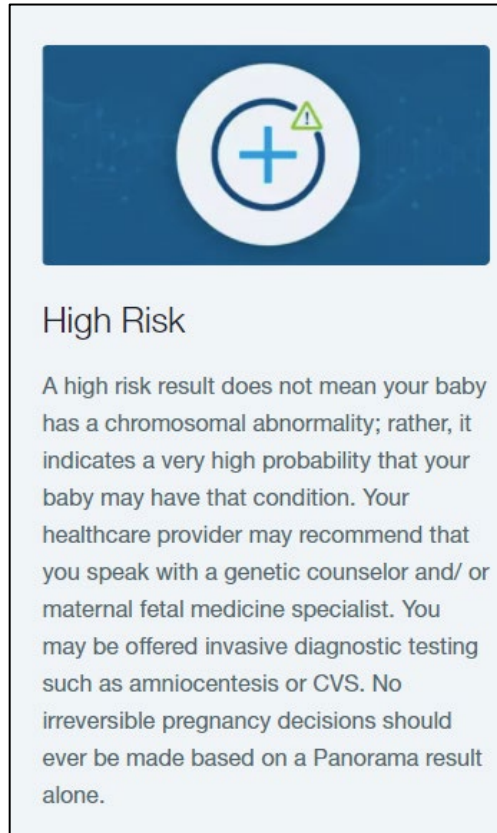
38. Natera's website advertises Panorama as having been tested with "the largest prospective NIPT study" with outcomes of "~90% samples with genetic truth."²⁸ The page also lists the numerous rare abnormalities Panorama screens for: Down Syndrome, Edwards Syndrome, Patau Syndrome, Turner Syndrome, Klinefelter Syndrome, Triple X Syndrome, Jacob's Syndrome, 22Q11.2 Deletion Syndrome, Prader-Willi Syndrome, Angelman Syndrome, 1p36 Deletion Syndrome, Cri-du-Chat Syndrome, and Triploidy.²⁹



²⁸ *Id.*

²⁹ *Id.*

39. Panorama, according to Natera's website, identifies whether a fetus is a "low risk" or "high risk" for genetic disease. A "high risk" finding, according to Natera, "indicates a **very high** probability that your baby may have [the] condition" identified.






40. In addition, while Natera specifically highlights the high "positive predictive value" or PPV of Panorama for Down syndrome (also known as trisomy 21), which conveys the message that its NIPT tests are accurate, it obscures that the PPV for the rarer genetic conditions Panorama screens for is as low as 2-5%.



41. Panorama's patient brochure, as of July 2021, touted that Panorama has "fewer false positives and fewer false negatives." ECF No. 31-6.


How is Panorama different?

Panorama is the only NIPT that can tell the difference between the mother's and the baby's DNA, which results in:

-  Fewer false positives and fewer false negatives^{1,2,3}
-  The highest reported fetal sex accuracy of any NIPT (fetal sex reporting is optional)^{1,2,3}
-  The ability to detect triploidy, a severe chromosomal abnormality that can result in serious pregnancy complications if unmonitored^{6,7}

42. In a similar brochure targeted at doctors, Natera makes similar claims about the accuracy of its products, boasting that its tests are "validated with >99% sensitivity & specificity." Natera urges, "[f]or more clinically relevant information, combine Panorama, with Vistara, the next innovation in NIPT technology."³⁰

Vistara is validated with >99% sensitivity & specificity²



LETTERS

<https://doi.org/10.1038/s41591-018-0334-x>

Non-invasive prenatal sequencing for multiple Mendelian monogenic disorders using circulating cell-free fetal DNA

Clinical outcomes	n
True positives	20
False positives	0
True negatives	127
False negatives	0

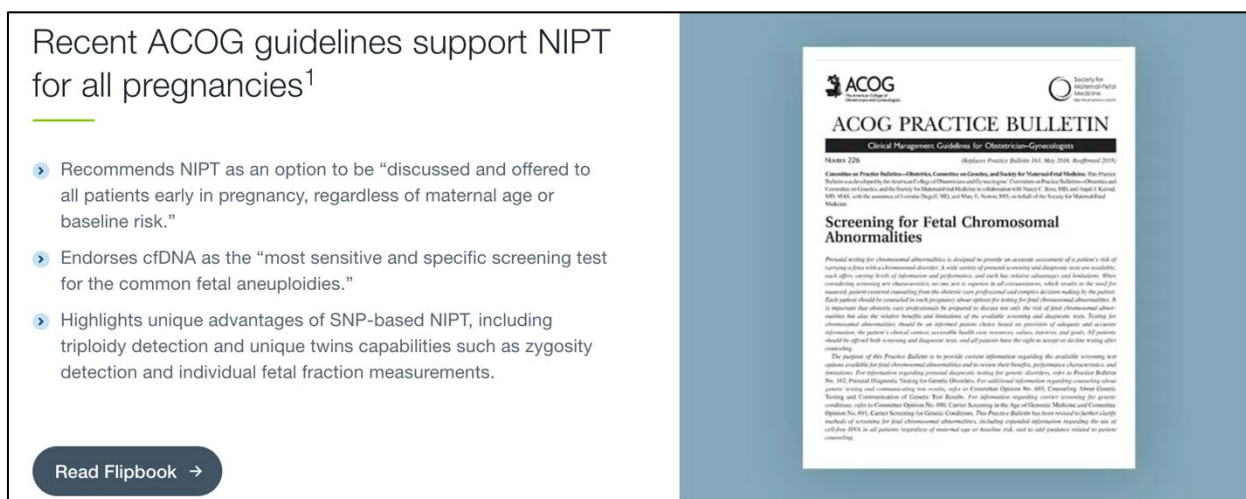
43. In response to the question "what are the benefits of having the Panorama prenatal screen?" on a FAQ page, Natera says: "Non-invasive and highly accurate, Panorama identifies more than 99% of pregnancies affected with Down syndrome and has the lowest reported false positive rate of

³⁰ <https://www.natera.com/resource-library/panorama/panorama-vistara-physician-brochure>.

any prenatal screening test for the commonly screened chromosomal abnormalities: trisomy 21, trisomy 18, and trisomy 13.”³¹

44. Natera advertises that its NIPT test does not present the risks associated with the more accurate but invasive diagnostic tests, touting that “Panorama poses no risk to the baby compared to amniocentesis or chorionic villus sampling (CVS).”³² It also prominently advertises that its test can be performed “as early as nine weeks gestation.”³³

45. Natera also refers to recently changed ACOG guidelines, which now recommend screening be offered in all pregnancies, not just high-risk pregnancies. This recommendation increased the popularity of Natera’s NIPT tests and others on the market, but ACOG paired the recommendation with an advisory message that accurate information should be provided about the strengths and weaknesses of the various screening tests available:



46. On or around March 2022, approximately one month after this case was initially filed, Natera released a new version of its brochure. This version, among other things, added a QR-code link to PPVs, stated that a positive result “does not make a final diagnosis,” and removed a “peace of mind” testimonial. Even these changes, however, failed to disclose the numerous studies finding the PPV for various genetic conditions was low, and the false positive rate for various genetic conditions was high.

³¹ <https://www.natera.com/womens-health/panorama-nipt-prenatal-screening/faq/#pg-menu-tabs>.

³² <https://www.natera.com/womens-health/panorama-nipt-prenatal-screening>.

³³ *Id.*

47. Panorama, like other NIPT tests, is costly. Although Natera estimates that the average out-of-pocket cost for women is less than \$249,³⁴ it can often be much more expensive, costing thousands of dollars.³⁵

D. The Truth About the Accuracy and Reliability of Natera's NIPT Tests

48. While NIPT has recently expanded beyond Down syndrome to screen for rarer conditions, including chromosomal microdeletions, there has been a precipitous drop in the PPV of NIPT in testing for those conditions. The *New York Times* reported that NIPT for conditions associated with microdeletions such as DiGeorge syndrome (also known as 22q11.2 deletion), 1p36 deletion, Cri-du-chat syndrome, Wolf-Hirschhorn syndrome, Prader-Willi syndrome, and Angelman syndrome is wrong 81% to 93% of the time.³⁶ In addition, screenings for Triploidy, Patau syndrome (also known as trisomy 13) and Turner syndrome (also known as monosomy X) similarly generate a large percentage of false positives.³⁷ Despite the steep drop-off in the reliability of the tests and the serious implications of a positive result, Natera continues to stress their reliability.

49. Natera has known for years that Panorama is unreliable for microdeletion-related and other rare conditions from its own testing and external sources. In early 2016, for instance, Natera took note that data published in the January 2016 issue of *Ultrasound in Obstetrics & Gynecology* showed that Panorama had a PPV of only 18% for DiGeorge syndrome.³⁸ In that study involving high-risk cases, researchers found that diagnostic testing for 61 cases “confirmed 11 (18.0%) true positives and identified 50 (82.0%) false positives, resulting in a positive predictive value (PPV) of 18.0%.”³⁹ Natera also knows that doctors rely on company representations about the accuracy of their NIPT tests. Several

³⁴ <https://www.natera.com/wp-content/uploads/2021/01/PTP-Billing-Guide-2020-English.pdf>.

³⁵ <https://www.genomeweb.com/molecular-diagnostics/natera-accused-unfair-deceptive-billingpractices-related-nipt-services-new#.YdSpvmjMKUk>.

³⁶ <https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html>.

³⁷ *Id.*

³⁸ <https://investor.natera.com/static-files/168603f8-131d-4a94-84e1-e898afdd073d>.

³⁹ <https://pubmed.ncbi.nlm.nih.gov/26396068/>.

1 studies have shown that academic studies with industry involvement, as well as actual marketing
2 materials, inform how clinicians communicate about NIPT to patients.⁴⁰

3 50. In a 2017 study entitled *Positive Predictive Value Estimates for Cell-Free Noninvasive*
4 *Prenatal Screening From Data of a Large Referral Genetic Diagnostic Laboratory*,⁴¹ researchers
5 analyzed the PPV and false positive rate for various conditions tested by NIPT tests like Natera's. The
6 results did not inspire great confidence in the reliability of Panorama. For instance, the study found (i)
7 the PPV for Trisomy 13 was 45% while the false positive rate was 55%; (ii) the PPV for Monosomy X
8 was 27% while the false positive rate was 73%; (iii) "[t]he combined PPV for all microdeletion-positive
9 cffDNA screen cases ... was 13%"; and (iv) "the PPV for the most frequent microdeletion ...
10 (22q11.2/DiGeorge syndrome deletion []) was 21%."⁴²

11 51. Due to the rarity of many of the conditions tested, NIPT tests like Panorama can return
12 more false positives than the number of test subjects who actually have the underlying condition. For
13 instance, DiGeorge syndrome affects about one out of every 4,000 births. Thus, in a random sample of
14 100,000 births, only about 25 would be expected to have DiGeorge syndrome, and the remaining 99,975
15 would not.⁴³ Of that sample, a test with a "99.9% reliability" rate would thus identify about 25 true
16 positive results (99.9% of 25) and about 100 false positives (0.1% of 99,975).⁴⁴ So, out of 125 positive
17 test results for DiGeorge in this example, only 20 percent of the positive test results would be accurate.
18 "This means that if an expecting mother receives a positive test for DiGeorge syndrome, there is only a
19

20 ⁴⁰ R. M. Farrell *et al.*, "The Use of Noninvasive Prenatal Testing in Obstetric Care: Educational
21 Resources, Practice Patterns, and Barriers Reported by a National Sample of Clinicians," *Prenatal*
22 *Diagnosis* 36, no. 6 (2016): 499-506; L. Parham, M. Michie, and M. Allyse, "Expanding Use of cfDNA
23 Screening in Pregnancy: Current and Emerging Ethical, Legal, and Social Issues," *Current Genetic*
24 *Medicine Reports* 1, no. 5 (2017): 44-53.

25 ⁴¹ Andrea K. Petersen *et al.*, *Positive Predictive Value Estimates for Cell-Free Noninvasive Prenatal*
26 *Screening From Data of a Large Referral Genetic Diagnostic Laboratory*, 691 AM. J. OBSTETRICS &
27 GYNECOLOGY 1 (2017), available at <https://reader.elsevier.com/reader/sd/pii/S0002937817311870?token=89FFF7B59F5BB61B32E4961C89BE3EC80A013346930C7FE6CE514FC3FF725FC2CAF95732684F8F2A61723A4C9D285C7F&originRegion=us-east-1&originCreation=20230419200153>.
28

⁴² *Id.* at 3.

⁴³ *Id.*

⁴⁴ <https://int.nyt.com/data/documenttools/the-misleading-math-of-prenatal-tests-answer-key/4ace5309f9054a76/full.pdf>.

20 percent chance the fetus actually has the syndrome (a far cry from 99.9 percent). In other words, there is an 80 percent chance that the test is wrong.”⁴⁵

52. Some of the conditions Natera’s Panorama tests for have a positive predictive value as low as 2-5%, meaning positive test results *will be wrong as much as 98% of the time*. Despite these low accuracy rates—and the significant impact the test may have on a parent’s decision whether to continue with a pregnancy—Natera promotes Panorama as reliable overall, prominently emphasizing the accuracy rates of the tests for more common conditions like Down Syndrome that Panorama can reasonably detect.

53. With accuracy and reliability rates this low, positive test results have little if any utility. As one obstetrician and geneticist quoted in *The New York Times* put it, “It’s a little like running mammograms on kids ... The chance of breast cancer is so low, so why are you doing it?”⁴⁶

54. Reproductive Biomedicine & Society Online reported that patients are increasingly relying on the internet for healthcare information, which carries a corresponding increase in the risk of reliance on unclear or misleading information about NIPT.⁴⁷ The analysis found “a high degree of variability in the presentation of information about NIPT,”⁴⁸ including “most concerningly that companies, including Natera, described NIPT as a screening or diagnostic test unevenly, a key distinction for understanding the accuracy of results and easily misunderstood by patients if not presented clearly.”⁴⁹

55. The *Times* similarly reported that “[g]enetic counselors who have dealt with false positives say some doctors may not understand how poorly the tests work. And even when caregivers do correctly interpret the information, patients may still be inclined to believe the confident-sounding results sheets.”⁵⁰

⁴⁵ <https://www.nytimes.com/2022/02/10/learning/lesson-plans/the-misleading-math-of-prenatal-tests.html>.

⁴⁶ <https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html>.

⁴⁷ Ruth M. Farrell, Patricia K. Agatista, *et al.*, Online direct-to-consumer messages about non-invasive prenatal genetic testing, *Reproductive Biomedicine & Society Online*, March 10, 2016, available at [https://www.rbmsociety.com/article/S2405-6618\(16\)00003-4/fulltext](https://www.rbmsociety.com/article/S2405-6618(16)00003-4/fulltext).

⁴⁸ *Id.*

⁴⁹ <https://www.documentcloud.org/documents/21179846-cfa-sec-natera-letter>.

⁵⁰ <https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html>.

E. Reporting and Scrutiny of the NIPT Industry

56. In January 2022, the *Times* reported widespread misrepresentations on the accuracy of NIPT. The *Times*' analysis found that approximately 85% of the time, positive results from tests screening for rare chromosomal microdeletion disorders such as DiGeorge and Prader-Willi syndromes were incorrect.⁵¹

57. The *Times* also reported that companies offering NIPT were not transparent about the true accuracy of their tests. "The *Times* reviewed 17 patient and doctor brochures from eight of the testing companies, including Natera, Labcorp, Quest and smaller competitors. Ten of the brochures never mention that a false positive can happen. Only one mentioned how often each test gets positive results wrong."⁵²

58. The market for NIPT is not heavily regulated. "There are few restrictions on what test makers can offer. The FDA often requires evaluations of how frequently other consequential medical tests are right and whether shortfalls are clearly explained to patients and doctors. But the FDA does not regulate this type of test."⁵³

59. Patients and doctors are easily confused by the marketing of companies like Natera. According to the *Times*, a former FDA official "reviewed marketing materials from three testing companies and described them as 'problematic.'" As he put it, "These numbers are meaningless."⁵⁴

60. After the *Times* released its report, Natera continued to insist that its NIPT test is accurate and reliable. On January 3, 2022, Natera issued a press release disputing the report's analysis, insisting that its Panorama test is accurate in over 99% of cases.⁵⁵ During a February 24 conference call Natera's chief executive similarly claimed that Panorama test results are accurate more than 99.9% of the time for both high and low risk patients.

61. Also in January 2022, the Campaign for Accountability sent a letter to the U.S. Securities and Exchange Commission ("SEC") detailing the misleading nature of NIPT marketing and

⁵¹ *Id.*

⁵² *Id.*

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ <https://www.natera.com/company/nat-news/recent-news-coverage/>; but see *id.* (acknowledging that "Natera's microdeletion test has PPVs ranging from ~5% to 50%").

1 requesting that the SEC “investigate whether Natera, Inc. has misled investors in violation of the
 2 Securities Act of 1934.”⁵⁶ The letter outlines the misleading nature of Natera’s NIPT results, and
 3 encourages the SEC to investigate the “company’s effort to persuade pregnant women and their doctors
 4 of the efficacy of NIPTs” to determine “whether Natera knowingly overstated the accuracy of its
 5 NIPT.”⁵⁷

6 62. Natera has been found to have engaged in deceitful business conduct. On March 14,
 7 2022, a jury in the District of Delaware awarded CareDx, a competing medical testing company, \$44.9
 8 million and found that Natera had engaged in false advertising and promotion regarding its kidney
 9 transplant assessment test, and had misled medical professionals, patients, and insurers.⁵⁸

10 63. In April 2022, the FDA issued a safety communication about NIPT (also called non-
 11 invasive prenatal screening or NIPS) tests, warning that “Genetic Non-Invasive Prenatal Screening Tests
 12 May Have False Results.”⁵⁹ The statement, directed to “patients and health care providers,” emphasizes
 13 that “[w]hile health care providers widely use NIPS tests, none have yet been authorized, cleared, or
 14 approved by the FDA” and “[t]he accuracy and performance of NIPS tests have not been evaluated by
 15 the FDA and these tests can give false results.”

16 64. The FDA safety communication notes that the FDA is aware of reports that “pregnant
 17 people have ended pregnancies based only on the results of NIPS tests,” and states that “[g]iven the
 18 increased use of these tests and concerns raised in recent media reports, the FDA is providing this
 19 information to educate patients and health care providers and to help reduce the inappropriate use of
 20 NIPS tests.”⁶⁰ The FDA safety communication also states that patients and health care providers alike
 21 “should be aware of the risks and limitations of using these screening tests,” and makes specific
 22 recommendations for patients and for health care providers to become better informed.

23 65. Further, the FDA safety communication notes “the risks related to the use of genetic
 24 prenatal screening and the potential harm if NIPS test results are not used and interpreted appropriately”
 25

26 ⁵⁶ <https://www.documentcloud.org/documents/21179846-cfa-sec-natera-letter>.

27 ⁵⁷ *Id.*

28 ⁵⁸ *See CareDx, Inc. v. Natera, Inc.*, No. 19-cv-662-CFC-CJB (D. Del.), ECF No. 329.

⁵⁹ <https://www.fda.gov/medical-devices/safety-communications/genetic-non-invasive-prenatal-screening-tests-may-have-false-results-fda-safety-communication>.

⁶⁰ *Id.*

1 and “encourages test developers to provide accurate, clear, and complete information about the
2 performance of their tests, how they should be used, and what the results may or may not mean.”⁶¹

3 66. Separately, in early 2022, a report by the Hastings Center (a nonpartisan, bioethics
4 nonprofit) “analyze[d] all available English-language consumer-directed NIPT brochures,” and
5 concluded that the communications “substantiate concerns about bias and inaccuracy in the promotion
6 of these screening tests.”⁶² A brochure for Natera’s Panorama NIPT was one of the brochures
7 analyzed.⁶³

8 67. The Hastings Report observes that “when these marketing materials are incomplete,
9 unsubstantiated, inaccurate, misleading, or emotive, the consumer’s ability to make informed choices is
10 compromised” and notes that “[p]oor-quality information poses the potential for harm from increased
11 shock, distress, and confusion upon receipt of a high-chance result and may even lead to termination of
12 an unaffected fetus if the possibility of a false-positive result is not clearly communicated.”⁶⁴

13 68. The report explains that “many of the promotional brochures had the potential to confuse
14 would-be parents about what results actually show,” and why.⁶⁵ The report identifies several common
15 aspects of NIPT company communications that are misleading to consumers.

16 69. **PPV rates:** “NIPT brochures should include sensitivity and PPV, rates of test failure,
17 and reference to recent, high-quality data. Only 18 percent of the for-profit brochures offered sensitivity
18 and PPV for each condition screened, and 50 percent discussed possible test failure.”⁶⁶

19 70. **Diagnostic vs. screening:** The Hastings Report cited three essential points to clearly
20 communicating the difference between diagnostic testing and screening: 1) NIPT should be clearly
21

22 ⁶¹ *Id.*

23 ⁶² Kelly Holloway, Nicole Simms, Robin Z. Hayeems & Fiona A. Miller, “The Market in Noninvasive
24 Prenatal Tests and the Message to Consumers: Exploring Responsibility,” Hastings Center Report 52
25 (2022) (“Hastings Report”) at 1, 3 ([https://www.documentcloud.org/documents/21411047-simms-ev-
feb-9](https://www.documentcloud.org/documents/21411047-simms-ev-feb-9)).

26 ⁶³ Hastings Report Tables 1-5 and Methods, [https://www.thehastingscenter.org/wp-
content/uploads/simms-supplementary-materials.pdf](https://www.thehastingscenter.org/wp-content/uploads/simms-supplementary-materials.pdf).

27 ⁶⁴ Hastings Report at 2, 3.

28 ⁶⁵ C. Clark, *Prenatal Blood Test Info Often Misleads, Endangering Normal Pregnancies*, MedPage
Today, <https://www.medpagetoday.com/special-reports/exclusives/97654>.

⁶⁶ Hastings Report at 5 (citing the Nuffield Council on Bioethics’ guidelines for NIPT company
communications).

presented as a screening test, 2) it should not be represented as a replacement for invasive diagnostic testing, and 3) it should communicate that positive results must be confirmed through diagnostic testing.⁶⁷ The Hastings Report evaluated the NIPT brochures against the standards recognized by the Nuffield Council on Bioethics (the “Council”) and found that most companies offer misleading or conflicting information on this distinction, and “only 21% of for-profit companies’ NIPT brochures” had all three⁶⁸:

(a) First, “Many brochures were consistently unclear about distinguishing NIPT as a screening versus diagnostic test. Less than half (43 percent) of the for profit companies’ brochures clearly indicated that NIPT is not diagnostic.”⁶⁹

(b) Second, “Almost two-thirds (64 percent) of for-profit companies’ brochures represented NIPT as a replacement for or alternative to invasive testing.”⁷⁰

(c) Third, even though “[m]any brochures (64 percent) from for-profit companies did indicate that a positive result should be followed up with a diagnostic test,” the Hastings Report notes that conflicting information can “confuse consumers about the test’s capabilities. For example, a brochure could be clear about the fact that a test was a screening and not a diagnostic test, suggesting that a positive result on the screening test must be followed up with a diagnostic test—but could in other places represent NIPT as a replacement for invasive testing by presenting it as a way to ‘avoid unnecessary, risky invasive procedures such as amniocentesis and chorionic villus sampling.’”⁷¹

71. **Test implications:** The Council also “advises NIPT companies against suggesting that their tests will offer consumers reassurance or ‘peace of mind.’” Nevertheless, the Hastings Report found that 43 percent of for-profit companies’ brochures did present their tests this way.⁷²

72. **Claims of legitimacy despite a lack of regulatory oversight:** The Hastings Report further found that “[a]lthough statutory regulation evaluating NIPT for safety and efficacy before market

⁶⁷ *Id.* at 5 (citing the Nuffield Council on Bioethics’ guidelines).

⁶⁸ *Id.* at 5-6.

⁶⁹ *Id.* at 5.

⁷⁰ *Id.*

⁷¹ *Id.* at 6 (quoting an NIPT brochure).

⁷² *Id.*

access is not required, our concept-driven coding revealed consistent references to a number of entities involved in ‘regulating’ or guiding the manufacturing, use, or analysis of molecular diagnostics—particularly in the brochures from for-profit companies.”⁷³ “These references to external authorities were often made in relation to claims about test safety, accuracy, or quality” and “almost every brochure (93 percent of the for-profit and 100 percent of the nonprofit brochures) stated that their NIPT was ‘accurate,’ ‘reliable,’ and/or ‘precise.’”⁷⁴

73. The report concludes that common reference “to external authorities such as the College of American Pathologists ... could impart the impression that the test itself has been externally validated by such regulations and entities, even though that is not their function. Consumers who are attempting to make a decision about whether to use NIPTs are therefore presented with potentially misleading information.”⁷⁵

74. **Physicians as an authority:** In addition, the Hastings Report notes that consumers are commonly directed to the physician as a form of authority, despite the fact that “several studies indicate limitations in physicians’ understanding of NIPT’s function and results or a lack of confidence in their ability to communicate with patients about it.”⁷⁶ “This problem is compounded by the fact that most physicians offering advice to consumers are not specialists in the area of prenatal screening, and there is evidence that they rely, at least in part, on information produced by the companies in order to inform their patients.”⁷⁷

⁷³ *Id.*

⁷⁴ *Id.* at 7.

⁷⁵ *Id.*

⁷⁶ *Id.* at 7-8 (citing L. Haymon *et al.*, “Clinical Implementation of Noninvasive Prenatal Testing among Maternal Fetal Medicine Specialists,” *Prenatal Diagnosis* 34, no. 5 (2014): 416-23; P. Swaney *et al.*, “Attitudes and Knowledge of Maternal-Fetal Medicine Fellows regarding Noninvasive Prenatal Testing,” *Journal of Genetic Counseling* 1, no. 25 (2016): 73-78; P. Benn *et al.*, “Obstetricians and Gynecologists’ Practice and Opinions of Expanded Carrier Testing and Noninvasive Prenatal Testing,” *Prenatal Diagnosis* 34, no. 2 (2014): 145-52.).

⁷⁷ *Id.* at 8 (citing R. M. Farrell *et al.*, “The Use of Noninvasive Prenatal Testing in Obstetric Care: Educational Resources, Practice Patterns, and Barriers Reported by a National Sample of Clinicians,” *Prenatal Diagnosis* 36, no. 6 (2016): 499-506; L. Parham, M. Michie, and M. Allyse, “Expanding Use of cfDNA Screening in Pregnancy: Current and Emerging Ethical, Legal, and Social Issues,” *Current Genetic Medicine Reports* 1, no. 5 (2017): 44-53; ; A. C. Jelin *et al.*, “Obstetrician and Gynecologists’

75. Natera's brochures and other marketing material have many of the misleading characteristics identified by the Hastings Report.

(a) **PPV rates:** Natera did not advise consumers, including Plaintiffs, of the PPV rate of Panorama's tests. No information about PPVs is provided in Natera's current brochure.⁷⁸ The current version of Natera's website touts the high "positive predictive value" or PPV of Panorama for Down syndrome but does not pair that figure with the very low PPV for rarer genetic conditions.



(b) **Diagnostic vs. screening:** Natera falsely implies that Panorama is a replacement for invasive diagnostic testing, advertising that its NIPT test does not pose the risks associated with diagnostic tests: "Panorama poses no risk to the baby compared to amniocentesis or chorionic villus sampling (CVS)."⁷⁹

(c) **Test implications:** Natera's Panorama brochure suggests that its test will give consumers peace of mind by offering the ability to "Discover more about your baby's health" and including a testimonial from a mother who says she is "now planning a birth at a regular maternity ward instead of closer to the children's hospital thanks to this painless test!"⁸⁰

Population-Based Screening Practices," *Journal of Maternal- Fetal & Neonatal Medicine* 29, no. 6 (2016): 875-79; P. Swaney *et al.*, "Attitudes and Knowledge of Maternal-Fetal Medicine Fellows regarding Noninvasive Prenatal Testing," *Journal of Genetic Counseling* 1, no. 25 (2016): 73-78).

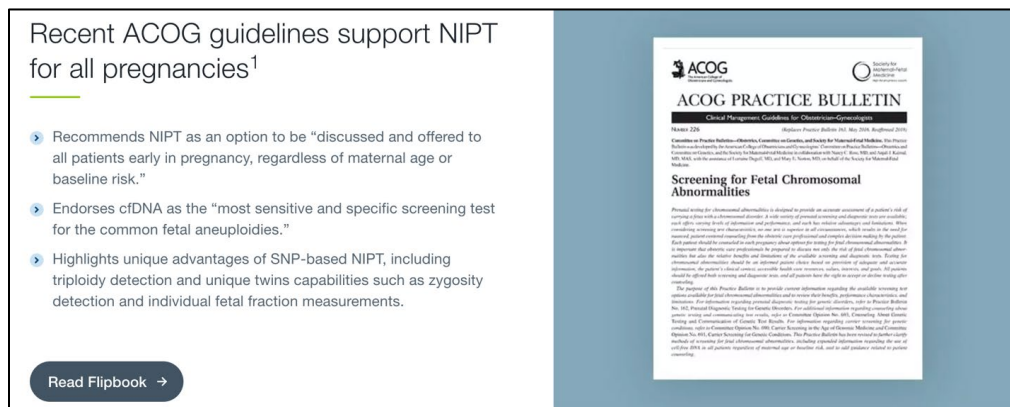
⁷⁸ <https://www.natera.com/resource-library/panorama/panorama-patient-brochure>.

⁷⁹ <https://www.natera.com/womens-health/panorama-nipt-prenatal-screening>.

⁸⁰ <https://www.natera.com/resource-library/panorama/panorama-patient-brochure>.

(d) **Claims of legitimacy despite a lack of regulatory oversight:** Natera advertises Panorama as “the most rigorously validated NIPT.”⁸¹ Natera’s website, for example, advertises Panorama as having been tested with “the largest prospective NIPT study” and makes vague, reassuring claims of outcomes of “~90% samples with genetic truth.”⁸²

(e) Just as the Hastings Report concludes that common reference “to external authorities such as the College of American Pathologists ... could impart the impression that the test itself has been externally validated by such regulations and entities,”⁸³ Natera prominently cites the ACOG guidelines, which now recommend screening be offered in all pregnancies.⁸⁴



(f) **Physicians as an authority:** Just as in the brochures criticized in the Hastings Report, Natera directs consumers to consult with their doctors about the test. Also, as identified as problematic in that report, Natera markets Panorama to doctors with many of the same misleading claims of accuracy that doctors lack the expertise to evaluate. For example, in a brochure targeted at doctors, an image from which is reproduced below, Natera makes similar claims about the accuracy of its products, boasting that its tests are “validated with >99% sensitivity & specificity.” Natera urges, “[f]or more clinically relevant information, combine Panorama, with Vistara, the next innovation in NIPT technology.”⁸⁵

⁸¹ <https://www.natera.com/womens-health/panorama-nipt-prenatal-screening>.

⁸² *Id.*

⁸³ *Id.*

⁸⁴ <https://www.natera.com/womens-health/panorama-nipt-prenatal-screening/average-risk/#pg-menu-tabs>.

⁸⁵ <https://www.natera.com/resource-library/panorama/panorama-vistara-physician-brochure>.



F. Consequences of a False Positive Test Result

76. A positive result on a prenatal test indicating that an unborn child has a genetic abnormality has far-reaching impacts on a pregnant patient.

77. Prospective parents fear that their pregnancy may not be viable, or that even if the child survives birth, it will be seriously impacted by a genetic disorder. The health implications of these conditions on the fetus, and the potential economic consequences of caring for a child born with genetic abnormalities, are so serious that many patients with a positive result consider whether to terminate the pregnancy. Some patients do terminate their pregnancies as a result of the positive test results.

78. One United Kingdom study in 2017 found that that 63% of U.K. women with high-risk NIPT results go on to terminate their pregnancies.⁸⁶

79. Compounding the difficult choice patients face about whether to continue the pregnancy, NIPT is usually performed early in a pregnancy before further diagnostic testing can definitively confirm whether the fetus truly is impacted. Even if diagnostic testing is available, it is highly invasive and there is a risk that the test itself will cause a miscarriage. And in some states where terminating a pregnancy is more tightly restricted, a parent with a positive test result may not have the option to wait for a diagnostic test before deciding whether to terminate.

80. In addition to the anguish for the potentially compromised health of their child, parents with positive test results also must contend with the prospect of expensive and stressful doctor's appointments with high-risk pregnancy specialists, often incurring increased costs for these extra visits and increased testing. As the *Times* reported, "Patients who receive a positive result are supposed to pursue follow-up testing, which often requires a drawing of amniotic fluid or a sample of placental

⁸⁶ M. Hill *et al.*, "Has Noninvasive Prenatal Testing Impacted Termination of Pregnancy and Live Birth Rates of Infants with Down Syndrome?," *Prenatal Diagnosis* 37, no. 13 (2017): 1281-90.

1 tissue. Those tests can cost thousands of dollars, come with a small risk of miscarriage and can't be
2 performed until later in pregnancy—in some states, past the point where abortions are legal.”⁸⁷

3 81. The *Times* also reported that “[t]he companies have known for years that the follow-up
4 testing doesn't always happen. A 2014 study found that 6 percent of patients who screened positive
5 obtained an abortion without getting another test to confirm the result. That same year *The Boston*
6 *Globe* quoted a doctor describing three terminations following unconfirmed positive results.”⁸⁸

7 82. False positives can and do lead to tragic results: “the follow-up testing revealed the fetus
8 was healthy. But by the time the results came, the patient had already ended her pregnancy.”⁸⁹

9 **G. Plaintiffs' Experiences with Natera's Panorama Test**

10 **1. Lisa Cassinis**

11 83. Plaintiff Lisa Cassinis became pregnant in 2020. When she was in her first trimester, she
12 purchased a Natera Panorama NIPT test. Before doing so, she reviewed Defendant's Panorama NIPT
13 test brochure.

14 84. Cassinis's test results indicated that her unborn child was high risk for serious genetic
15 conditions, including triploidy and trisomy 13.

16 85. Cassinis's test results also gave details about each condition. They explained that
17 “Almost all pregnancies with triploidy miscarry” and “The few babies that are born with triploidy
18 usually do not live past a few days of life.” For trisomy 13, also called Patau syndrome, the results note
19 that affected babies “often have serious birth defects and survivors experience severe intellectual
20 disability.”

21 86. Natera did not disclose to Cassinis that, contrary to its claims that Panorama is highly
22 accurate and reliable, the test is far less reliable and of little utility when screening for rare genetic
23 conditions.

24 87. As a result of her Panorama test results, and despite concerns about the invasive nature of
25 the test, Cassinis agreed to undergo CVS. The CVS test results indicated that her child did not have a
26 genetic abnormality and the Panorama results were a false positive. Still, she underwent continued
27

28 ⁸⁷ <https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html>.

⁸⁸ *Id.*

⁸⁹ *Id.*

1 monitoring until the birth of her child. She saw a cardiac specialist, continued to see a maternal and
2 fetal medicine specialist after that, and her child had a heart test when he was born. Her son was born
3 healthy.

4 88. Cassinis suffered substantial distress as a result of the false positive Natera test result.
5 She considered terminating and worried she might miscarry. Despite a normal CVS result, she was not
6 certain that her child was healthy until he was born.

7 89. In addition to purchasing the Natera test itself, Cassinis also incurred expenses for
8 significant follow up medical appointments and testing as a result of the Panorama results. She paid
9 nearly \$200 for the Natera test itself, hundreds of dollars for genetic counseling, and thousands of
10 dollars for the CVS test, related lab fees, and subsequent monitoring.

11 90. Nowhere in Natera's testing brochure, on its website, or in its marketing materials did
12 Natera disclose the low PPV and high false positive rates associated with many of the conditions for
13 which Panorama tests. Nor did Natera disclose in any marketing materials that, as a result of these
14 deficiencies and others alleged herein, the Panorama test could not accurately or reliably determine
15 whether Cassinis' baby had or was at risk of having a genetic abnormality.

16 91. Had Natera disclosed that the Panorama NIPT was neither accurate nor reliable to test for
17 the majority of genetic conditions it purported to identify, Cassinis would not have purchased it, or
18 would have paid significantly less for it. In addition to the other harm described herein, Cassinis
19 suffered emotional distress, stress, and anxiety as a result of the unreliable Natera NIPT test she
20 received.

21 2. Sara Martinez

22 92. Plaintiff Sara Martinez became pregnant in 2021. When she was in her first trimester, in
23 approximately February 2022, she purchased a Natera Panorama NIPT test. Before doing so, she
24 encountered descriptions of the product. She also reviewed Defendant's Panorama NIPT test brochure
25 with her test results.

26 93. Martinez's test results indicated that her unborn child had an atypical finding on sex
27 chromosomes, including potential Turner Syndrome, a serious genetic condition.
28

1 94. Natera did not disclose to Martinez that, contrary to its claims that Panorama is highly
2 accurate and reliable, the test is far less reliable and of little utility when screening for many rare genetic
3 conditions.

4 95. As a result of her Panorama test results, and despite concerns about the invasive nature of
5 the test, Martinez agreed to undergo CVS. The CVS test results indicated that her child does not have a
6 genetic abnormality and the Panorama results were a false positive. Her baby was born healthy.

7 96. Martinez suffered substantial distress as a result of the false positive Natera test result.
8 She considered terminating, and worried that she might miscarry. Despite the CVS test result, she was
9 not certain that her child was healthy until its birth.

10 97. In addition to purchasing the Natera test itself, Martinez incurred expenses for significant
11 follow up medical appointments and testing as a result of the Panorama results. Martinez was charged
12 approximately \$1,100 for these additional doctors' appointments and tests.

13 98. Nowhere in Natera's testing brochure, on its website, or in its marketing materials did
14 Natera disclose the low PPV and high false positive rates associated with many of the conditions for
15 which Panorama tests. Nor did Natera disclose in any marketing materials that, as a result of these
16 deficiencies and others alleged herein, the Panorama test could not accurately or reliably determine
17 whether Martinez's baby had or was at risk of having a genetic abnormality.

18 99. Had Natera disclosed that the Panorama NIPT was neither accurate nor reliable to test for
19 the majority of genetic conditions it purported to identify, Martinez would not have purchased it, or
20 would have paid significantly less for it. In addition to the other harm described herein, Martinez
21 suffered emotional distress, stress, and anxiety as a result of the unreliable Natera NIPT test she
22 received.

23 **3. Amanda Law**

24 100. Plaintiff Law became pregnant in 2018. In or about September 2018, when she was in
25 her first trimester, Plaintiff Amanda Law purchased and took a Natera Panorama NIPT test while
26 residing in Fort Lauderdale, Florida. Before doing so, Law reviewed Defendant's Panorama NIPT test
27 brochures and marketing materials on Defendant's website while in Florida.
28

1 101. Law received her test results on September 24, 2018. Law’s test results indicated that her
2 unborn child was high risk for serious genetic conditions, including Triploidy and Trisomy 13.

3 102. Law’s test results also gave details about each condition. The test results explained that
4 “an increased incidence of pregnancy loss has [] been observed with this result.” The test results went
5 on to state that “[p]regnancies with triploidy . . . or trisomy 13 tend to have smaller than average
6 placentas,” that “[i]n general, babies with one of these conditions have serious birth defects and
7 significantly shortened lifespans,” and that “[i]t is rare for a baby with triploidy to be liveborn.”

8 103. Natera did not disclose to Law that, contrary to its claims that Panorama is highly
9 accurate and reliable, the test is far less reliable and of little utility when screening for many rare genetic
10 conditions.

11 104. As a result of her Panorama test results, Law underwent subsequent monitoring by a
12 high-risk specialist. That monitoring indicated that her child did not have a genetic abnormality and the
13 Panorama results were a false positive.

14 105. Law paid for her Panorama NIPT test out-of-pocket because it was not covered by her
15 insurance. In addition to purchasing the Natera test itself, Law also incurred expenses for significant
16 follow up medical appointments and testing as a result of the Panorama results.

17 106. Law suffered substantial distress as a result of the false positive Natera test result and felt
18 immense pressure to terminate her pregnancy. Law chose to continue with her pregnancy and ultimately
19 gave birth to a healthy baby girl who did not suffer from any chromosomal abnormalities.

20 107. Nowhere in Natera’s testing brochure, on its website, or in its marketing materials did
21 Natera disclose the low PPV and high false positive rates associated with many of the conditions for
22 which Panorama tests. Nor did Natera disclose in any marketing materials that, as a result of these
23 deficiencies and others alleged herein, the Panorama test could not accurately or reliably determine
24 whether Law’s baby had or was at risk of having a genetic abnormality.

25 108. Had Natera disclosed that the Panorama NIPT was neither accurate nor reliable to test for
26 the majority of genetic conditions it purported to identify, Law would not have purchased it, or would
27 have paid significantly less for it. In addition to the other harm described herein, Law suffered
28 emotional distress, stress, and anxiety as a result of the unreliable Natera NIPT test she received.

1 **4. Lillian Delaurie**

2 109. Plaintiff Lilian Delaurie became pregnant in 2021. When she was in her first trimester, in
3 approximately February 2022, she purchased a Natera Panorama NIPT test. Before doing so, she
4 reviewed Defendant's Panorama NIPT test brochure.

5 110. Delaurie's test results indicated that her unborn child was high risk for serious genetic
6 conditions, including triploidy and trisomy 13.

7 111. Delaurie's test results also gave details about each condition. They explained that
8 "Almost all pregnancies with triploidy miscarry" and "The few babies that are born with triploidy
9 usually do not live past a few days of life." For trisomy 13, the results note that affected babies "often
10 have serious birth defects and survivors experience severe intellectual disability."

11 112. Natera did not disclose to Delaurie that, contrary to its claims that Panorama is highly
12 accurate and reliable, the test is far less reliable and of little utility when screening for many rare genetic
13 conditions.

14 113. Delaurie purchased another Panorama test, but the second set of results also showed high
15 risk for the same conditions.

16 114. Delaurie spoke with one of Natera's genetic counselors on or about March 7, 2022, who
17 told her that 99% of these tests are accurate.

18 115. As a result of her Panorama test results, and despite concerns about the invasive nature of
19 the test, Delaurie agreed to undergo amniocentesis. The amniocentesis test results indicated that her
20 baby did not have a genetic abnormality and the Panorama results were a false positive. Her baby was
21 born healthy.

22 116. Delaurie suffered substantial distress as a result of the false positive Natera test result.
23 She considered terminating, and worried that she might miscarry. Despite the amniocentesis test result,
24 she was not certain that her baby would be healthy until it was born.

25 117. In addition to purchasing the Natera test itself, Delaurie also incurred expenses for
26 significant follow up medical appointments and testing as a result of the Panorama results.

27 118. Nowhere in Natera's testing brochure, on its website, or in its marketing materials did
28 Natera disclose the low PPV and high false positive rates associated with many of the conditions for

1 which Panorama tests. Nor did Natera disclose in any marketing materials that, as a result of these
2 deficiencies and others alleged herein, the Panorama test could not accurately or reliably determine
3 whether Delaurie's baby had or was at risk of having a genetic abnormality.

4 119. Had Natera disclosed that the Panorama NIPT was neither accurate nor reliable to test for
5 the majority of genetic conditions it purported to identify, Delaurie would not have purchased it, or
6 would have paid significantly less for it. In addition to the other harm described herein, Delaurie
7 suffered emotional distress, stress, and anxiety as a result of the unreliable Natera NIPT test she
8 received.

9 **5. Laura Ashley Heryla**

10 120. Plaintiff Laura Ashley Heryla became pregnant in 2021. When she was in her first
11 trimester, she purchased a Natera Panorama NIPT test. Before doing so, she reviewed Defendant's
12 Panorama NIPT test brochure.

13 121. Heryla's test results indicated that her unborn child was high risk for serious genetic
14 conditions, including triploidy and trisomy 13.

15 122. Heryla's test results also gave details about each condition. They explained that "Almost
16 all pregnancies with triploidy miscarry" and "The few babies that are born with triploidy usually do not
17 live past a few days of life." For trisomy 13, the results note that affected babies "often have serious
18 birth defects and survivors experience severe intellectual disability."

19 123. Natera did not disclose to Heryla that, contrary to its claims that Panorama is highly
20 accurate and reliable, the test is far less reliable and of little utility when screening for many rare genetic
21 conditions.

22 124. As a result of her Panorama test results, Heryla sought treatment from a high-risk doctor.
23 Heryla underwent a second NIPT test, which indicated that her child likely did not have a genetic
24 abnormality and the first Panorama results were a false positive. Still, she underwent continued
25 monitoring with the high-risk doctor until the birth of her child. Her daughter was born healthy.

26 125. Heryla suffered substantial distress as a result of the false positive Natera test result. She
27 considered terminating if results were confirmed, and worried that she might miscarry. Despite the
28

1 second NIPT test result, she was not certain that her child was healthy until she was born and felt fear
2 throughout the entire pregnancy.

3 126. In addition to purchasing the Natera test itself, Heryla also incurred expenses for
4 significant follow up medical appointments and testing as a result of the Panorama results. She paid
5 over \$700 out of pocket for the Natera tests and over \$4,500 out of pocket for appointments with a high
6 risk doctor and associated tests and fees.

7 127. Nowhere in Natera's testing brochure, on its website, or in its marketing materials did
8 Natera disclose the low PPV and high false positive rates associated with many of the conditions for
9 which Panorama tests. Nor did Natera disclose in any marketing materials that, as a result of these
10 deficiencies and others alleged herein, the Panorama test could not accurately or reliably determine
11 whether Heryla's baby had or was at risk of having a genetic abnormality.

12 128. Had Natera disclosed that the Panorama NIPT was neither accurate nor reliable to test for
13 the majority of genetic conditions it purported to identify, Heryla would not have purchased it, or would
14 have paid significantly less for it. In addition to the other harm described herein, Heryla suffered
15 emotional distress, stress, and anxiety as a result of the unreliable Natera NIPT test she received.

16 **6. Yelena Kreynstein**

17 129. Plaintiff Kreynstein became pregnant in 2019. During her pregnancy, Plaintiff Yelena
18 Kreynstein's baby was diagnosed with a congenital heart defect that is sometimes associated with
19 DiGeorge syndrome. As a result, in April 2020, Plaintiff Kreynstein purchased and took a Natera
20 Panorama NIPT test in New Jersey to specifically test for DiGeorge syndrome. Before doing so,
21 Kreynstein reviewed Defendant's Panorama NIPT test brochures and marketing materials.

22 130. Kreynstein's test results indicated that her unborn child was high risk for DiGeorge
23 syndrome, which can cause many health issues, including heart defects, developmental delays, kidney
24 abnormalities, and cleft palates.

25 131. Natera did not disclose to Kreynstein that, contrary to its claims that Panorama is highly
26 accurate and reliable, the test is far less reliable and of little utility when screening for many rare genetic
27 conditions.

1 132. Kreynstein paid approximately \$200 out-of-pocket for the test. In addition to purchasing
2 the Natera test itself, Kreynstein also incurred expenses for significant follow up medical appointments
3 and testing as a result of the Panorama results.

4 133. Kreynstein suffered substantial distress as a result of the false positive Natera test result.
5 As a result of her Panorama test results, Plaintiff Kreynstein underwent amniocentesis, which indicated
6 that her child did not have DiGeorge syndrome and the Panorama results were a false positive.
7 Kreynstein ultimately continued with her pregnancy, and gave birth to a baby girl who did not suffer
8 from any chromosomal abnormalities but who has since had surgery to repair her heart defect.

9 134. Nowhere in Natera's testing brochure, on its website, or in its marketing materials did
10 Natera disclose the low PPV and high false positive rates associated with many of the conditions for
11 which Panorama tests. Nor did Natera disclose in any marketing materials that, as a result of these
12 deficiencies and others alleged herein, the Panorama test could not accurately or reliably determine
13 whether Kreynstein's baby had or was at risk of having a genetic abnormality.

14 135. Had Natera disclosed that the Panorama NIPT was neither accurate nor reliable to test
15 for the majority of genetic conditions it purported to identify, Kreynstein would not have purchased it, or
16 would have paid significantly less for it. In addition to the other harm described herein, Kreynstein
17 suffered emotional distress, stress, and anxiety as a result of the unreliable Natera NIPT test she
18 received.

19 **7. Chelsey Stephens**

20 136. Plaintiff Stephens became pregnant in 2022. In or about December 2022, when she was
21 in her first trimester, Stephens paid for and took a Natera Panorama NIPT test while residing in
22 Brooklyn, New York. Prior to paying for the Panorama NIPT test, Stephens encountered materials
23 prepared by Natera.

24 137. Stephens received her test results on December 16, 2022. Stephens' test results indicated
25 that her unborn child was at high risk for Monosomy X, which can cause many health issues, including
26 infertility, heart defects, diabetes, low thyroid hormone, and a high risk that the child would not be born
27 alive.
28

1 138. Natera did not disclose to Stephens that, contrary to its claims that Panorama is highly
2 accurate and reliable, the test is far less reliable and of little utility when screening for many rare genetic
3 conditions.

4 139. As a result of her Panorama test results, Stephens underwent subsequent monitoring by a
5 high-risk specialist. That monitoring included the purchase of further NIPT tests—which also returned
6 false positive results—and an invasive amniocentesis procedure. The amniocentesis procedure showed
7 that her child did not have a genetic abnormality and the Panorama NIPT test result was a false positive.

8 140. Stephens paid approximately \$75 out-of-pocket for the test. In addition to purchasing the
9 Natera test itself, Stephens also incurred expenses for significant follow-up medical appointments and
10 testing as a result of the Panorama results.

11 141. Stephens suffered substantial distress as a result of the false positive Natera test result and
12 felt immense pressure to terminate her pregnancy. Stephens chose to continue with her pregnancy,
13 which her amniocentesis results ultimately found was normal.

14 142. Nowhere in Natera's testing brochure, on its website, or in its marketing materials did
15 Natera disclose the low PPV and high false positive rates associated with many of the conditions for
16 which Panorama tests. Nor did Natera disclose in any marketing materials that, as a result of these
17 deficiencies and others alleged herein, the Panorama test could not accurately or reliably determine
18 whether Stephen's baby had or was at risk of having a genetic abnormality.

19 143. Had Natera disclosed that the Panorama NIPT was neither accurate nor reliable to test for
20 the majority of genetic conditions it purported to identify, Stephens would not have purchased it, or would
21 have paid significantly less for it. In addition to the other harm described herein, Stephens suffered
22 emotional distress, stress, and anxiety as a result of the unreliable Natera NIPT test she received.

23 **8. Amanda Davis**

24 144. Plaintiff Amanda Davis became pregnant in 2020. When she was in her first trimester,
25 she purchased a Natera Panorama NIPT test. Before doing so, she reviewed Defendant's Panorama
26 NIPT test brochure.
27
28

possible concerning their potential child, and so each has a desire to use Natera's NIPT Panorama test in the future. Natera, however, continues to provide misleading and incomplete information concerning the accuracy and reliability of its Panorama test. Given their experiences, Plaintiffs do not trust Natera's representations about its tests. As a result, although Plaintiffs would like to purchase Natera's Panorama test again, they will not do so unless Natera takes sufficient steps to effectively ensure the accuracy of its representations about the test.

VI. CLASS ACTION ALLEGATIONS

153. Plaintiffs bring this suit as a class action on behalf of themselves and all other persons similarly situated, pursuant to Federal Rules of Civil Procedure 23(a), (b)(2), and (b)(3), as representative of all persons who purchased for personal use Natera's NIPT testing services within the United States (the "Class").

154. In addition, Plaintiffs Cassinis and Martinez sue on behalf of a subclass consisting of all persons who purchased for personal use Natera's NIPT testing services within California (the "California Subclass"); Plaintiff Davis sues on behalf of a subclass consisting of all persons who purchased for personal use Natera's NIPT testing services within Ohio (the "Ohio Subclass"); Plaintiff Heryla sues on behalf of a subclass consisting of all persons who purchased for personal use Natera's NIPT testing services within Maryland (the "Maryland Subclass"); Plaintiff Delaurie sues on behalf of a subclass consisting of all persons who purchased for personal use Natera's NIPT testing services within Illinois (the "Illinois Subclass"); Plaintiff Kreynstein sues on behalf of a subclass consisting of all persons who purchased for personal use Natera's NIPT testing services within New Jersey (the "New Jersey Subclass"); Plaintiff Law sues on behalf of a subclass consisting of all persons who purchased for personal use Natera's NIPT testing services within Florida (the "Florida Subclass"); and Plaintiff Stephens sues on behalf of a subclass consisting of all persons who purchased for personal use Natera's NIPT testing services within New York (the "New York Subclass").

155. The Class and the state Subclasses are referred to collectively herein as the "Class." Excluded from the Class are Defendant, its affiliates, employees, officers and directors, and the Judge(s) assigned to this case. Plaintiffs reserve the right to modify, change or expand the Class and Subclass definitions based on discovery and further investigation.

1 156. This action is brought as a class action and may properly be so maintained pursuant to the
2 provisions of Rule 23 of the Federal Rules of Civil Procedure.

3 157. **Numerosity** – The members of the Class are so numerous that their individual joinder is
4 impracticable. While the exact number of individual Class members is unknown at this time, Plaintiffs
5 believe the information is in the possession of Natera, and that Class membership is determinable by
6 objective criteria using Defendant’s own records.

7 158. **Existence and Predominance of Common Question of Fact and Law** – There are
8 questions of law and fact common to the Class. These questions predominate over any questions
9 affecting only individual class members and include, but are not limited to:

- 10 (a) Whether Defendant’s NIPT test is accurate and reliable;
- 11 (b) Whether the marketing, advertising, packaging, labeling, and other
12 promotional materials for Panorama are deceptive;
- 13 (c) Whether Defendant has a duty to disclose the complete truth regarding the
14 accuracy and reliability of its NIPT test;
- 15 (d) Whether Defendant concealed material information about the accuracy and
16 reliability of its NIPT test results;
- 17 (e) Whether Defendant’s conduct violates the laws set forth in the causes of
18 action;
- 19 (f) Whether Plaintiffs and the Class have been harmed as a result of
20 Defendant’s conduct alleged herein;
- 21 (g) Whether Defendant has been unjustly enriched as a result of the conduct
22 alleged herein; and
- 23 (h) Whether Plaintiffs and the Class are entitled to declaratory and injunctive
24 relief.

25 159. **Typicality** – Plaintiffs’ claims are typical of the claims of the Class. Plaintiffs and the
26 Class were subjected to the same common pattern of conduct by Defendant, and Plaintiffs, like the other
27 members of the Class, sustained damages arising from Defendant’s violations of the law, as alleged
28 herein.

1 160. **Adequacy** – Plaintiffs will fairly and adequately represent and protect the interests of the
 2 Class and has retained competent counsel who are highly experienced in complex class actions and who
 3 intend to vigorously prosecute this action. There are no material conflicts between Plaintiffs and the
 4 members of the Class.

5 161. **Superiority** – A class action is superior to other available means for the fair and efficient
 6 adjudication of this dispute. The injury suffered by each individual Class member is relatively small in
 7 comparison to the burden and expense of prosecuting these claims individually. Individualized
 8 litigation also would risk inconsistent or contradictory judgments and increase the delay and expense to
 9 all parties and the courts. By contrast, a class action presents far fewer management difficulties and
 10 provides the benefits of single adjudication, economies of scale, and comprehensive supervision by a
 11 single court.

12 162. Class Certification is also appropriate under Rules 23(b)(1), (b)(2), and/or (c)(4) because:

- 13 • The prosecution of separate actions by individual members of the Class would create a
 14 risk of inconsistent or varying adjudications establishing incompatible standards of
 15 conduct for Natera.
- 16 • The prosecution of separate actions by individual Class members would create a risk of
 17 adjudications that would, as a practical matter, be dispositive of the interests of other
 18 Class members not parties to the adjudications, or would substantially impair or impede
 19 their ability to protect their interests.
- 20 • Natera has acted or refused to act on grounds generally applicable to the Class, making
 21 injunctive and corresponding declarative relief appropriate with respect to the Class as a
 22 whole; and
- 23 • The claims of class members are comprised of common issues whose resolution in a class
 24 trial would materially advance this litigation.

25 **VII. CAUSES OF ACTION**

26 **COUNT I**

27 **Violation of the Unfair Competition Law (Cal. Bus. & Prof. Code § 17200, *et seq.*) (“UCL”)**

28 163. Plaintiffs incorporate and reallege the foregoing allegations of fact.

1 additional unnecessary, invasive tests that involved a risk of miscarriage. They paid for and underwent
 2 substantial medical monitoring and attended unnecessary appointments with specialists and genetic
 3 counselors.

4 173. The gravity of the harm resulting from Natera's unfair conduct far outweighs any
 5 potential utility. Natera's Panorama test is of little use for identifying the presence of rare genetic
 6 conditions. For many genetic disorders, the Panorama test produces more false positives than true
 7 positives. Consumers reasonably expect a NIPT test to accurately and reliably predict a genetic
 8 abnormality at a rate significantly higher than 2-5%.

9 174. Natera's sharp practice of selling unreliable, often inaccurate NIPT tests harms the public
 10 at large and is part of a common and uniform course of wrongful conduct.

11 175. There are reasonably available alternatives that would further Natera's legitimate
 12 business interests. Natera could have produced more reliable prenatal tests or provided accurate
 13 warnings of the propensity of NIPT testing to yield false positives for serious genetic syndromes.

14 176. The harm from Natera's unfair conduct was not reasonably avoidable by consumers.
 15 Plaintiffs Cassinis and Martinez and California Subclass members, as well as their treating physicians,
 16 did not know, and had no reasonable means of discovering, that Natera's Panorama test produces a high
 17 rate of false positives and is unreliable.

18 177. Plaintiff Cassinis and Martinez and California Subclass members are therefore entitled to
 19 an injunction, restitution, and reasonable attorneys' fees including under California Code of Civil
 20 Procedure section 1021.5.

21 **COUNT II**

22 **Violation of the Song-Beverly Consumer Warranty Act (Cal. Civ. Code, § 1790, *et seq.*)**

23 178. Plaintiffs incorporate and reallege the foregoing allegations of fact.

24 179. Plaintiffs Cassinis and Martinez bring this claim on behalf of themselves and the
 25 California Subclass.

26 180. Plaintiffs Cassinis and Martinez are "buyers" within the meaning of California Civil
 27 Code section § 1791(b). Each purchased a Natera Panorama prenatal test in California.
 28

1 181. Natera is a manufacturer within the meaning of California Civil Code section 1791(j).
2 Natera is responsible for producing Natera prenatal tests; it directed and was involved in all stages of the
3 production and manufacturing processes.

4 182. Natera's Panorama prenatal test is a "consumer good[]" within the meaning of California
5 Civil Code section 1791(a).

6 183. Natera impliedly warranted to Plaintiffs Cassinis and Martinez that the Panorama
7 prenatal test each purchased was "merchantable" under California Civil Code sections 1791.1(a) and
8 1792.

9 184. Natera breached the implied warranty of merchantability by producing, manufacturing,
10 and selling Panorama prenatal tests that were not of merchantable quality. The Panorama prenatal test is
11 unreliable, producing a false positive the majority of the time for many genetic conditions. The test is
12 therefore unfit for the ordinary purposes for which prenatal tests are used—accurately detecting risk for
13 serious genetic conditions.

14 185. The unreliability in Natera's Panorama prenatal tests is latent. Test results are reported as
15 accurate, but the unreliability existed in the product at the time of sale. Plaintiffs and California
16 Subclass members had no reasonable means of discovering that Natera's NIPT tests are unreliable.
17 Accordingly, any subsequent discovery of the reliability beyond that time does not bar an implied
18 warranty claim under the Song-Beverly Act.

19 186. Any attempt by Natera to disclaim its implied warranty obligations under the Song-
20 Beverly Act is ineffective due to its failure to adhere to California Civil Code sections 1792.3 and
21 1792.4. Those sections provide that, in order to validly disclaim the implied warranty of
22 merchantability, a manufacturer must "in simple and concise language" state: "(1) The goods are being
23 sold on an 'as is' or 'with all faults' basis. (2) The entire risk as to the quality and performance of the
24 goods is with the buyer. (3) Should the goods prove defective following their purchase, the buyer and
25 not the manufacturer, distributor, or retailer assumes the entire cost of all necessary servicing or repair."
26 Therefore any attempted warranty disclaimer does not conform to sections 1792.3 and 1792.4.
27
28

187. As a direct and proximate cause of Natera's breaches of the Song-Beverly Consumer Warranty Act, Plaintiffs Cassinis, Martinez, and California Subclass members have been damaged in an amount to be proven at trial.

188. Plaintiffs Cassinis and Martinez seek costs and expenses, including reasonable attorneys' fees, under California Civil Code section 1794.

COUNT III

Violation of the Maryland Consumer Protection Act (Md. Code Ann. Com. Law § 13-101, *et seq.*)

189. Plaintiffs incorporate and reallege the foregoing allegations of fact.

190. Plaintiff Heryla brings this claim on behalf of herself and the Maryland Subclass.

191. Plaintiff Heryla and Maryland Subclass members are "consumers" within the meaning of Md. Code Com. Law § 13-101(c)(1).

192. Plaintiff Heryla, Maryland Subclass members, and Natera are "persons" within the meaning of Md. Code Com. Law § 13-101(h).

193. Natera's NIPT tests are "consumer goods" within the meaning of Md. Code Com. Law § 13-101(d)(2).

194. Maryland law prohibits unfair, abusive, or deceptive trade practices including any "[f]alse, falsely disparaging, or misleading oral or written statement, visual description, or other representation of any kind which has the capacity, tendency, or effect of deceiving or misleading consumers." Md. Code Com. Law § 13-301(1). Maryland law also prohibits representations that a consumer good has characteristics, use, benefit, or quantity which it does not have; the omission of a material fact if it deceives or tends to deceive; and the misrepresentation, knowing concealment, or omission of material fact with the intent that a consumer rely on the same in connection with the promotion or sale of a consumer good. *Id.* at 13-301(2), (3), (9).

195. Natera engaged in unfair acts and practices by developing and selling Panorama NIPT tests that were inaccurate and unreliable to test for a variety of genetic abnormalities. Natera derived a substantial financial benefit from its sale of these tests.

196. Natera engaged in deceptive, unfair and abusive practices by omitting material information for purposes of inducing consumers to purchase and submit to Natera for prenatal testing

1 services. Natera actively suppressed and failed to disclose material facts concerning the accuracy and
2 reliability of its NIPT test, including:

- 3 (a) knowingly and intentionally concealing from Plaintiffs, Class members, and their
4 physicians the fact that the Panorama test is inaccurate for many rare disorders, is highly
5 susceptible to false positives, and cannot be relied on to make critical decisions during a
6 pregnancy;
- 7 (b) failing to disclose that the PPV for rare but serious conditions such as Trisomy 13,
8 Monosomy X, and DiGeorge Syndrome is much lower, sometimes as low as 2-5%;
- 9 (c) failing to reveal that for rare disorders such as DiGeorge syndrome, there is actually an
10 80% or greater chance a positive result is wrong; and
- 11 (d) failing to disclose the high risk of false positives.

12 197. Natera owed Plaintiff Heryla and Maryland Subclass members a duty to disclose these
13 facts because Natera had exclusive and superior knowledge of them; because they would be material to
14 reasonable consumers; and because Natera intended for consumers to rely on the omissions in question.

15 198. Natera could have readily disclosed the truth regarding its Panorama NIPT tests to
16 Plaintiff and Maryland Subclass members through various sources, including its website, product
17 brochures and marketing materials, and through Plaintiff Heryla's and Maryland Subclass members'
18 physicians and health care providers.

19 199. Defendant's omissions were pervasive and deceived Plaintiff Heryla and Maryland
20 Subclass members, and have a tendency to deceive the general public regarding the reliability and value
21 of Panorama NIPT tests. The omissions by Natera alleged herein were material in that a reasonable
22 person would attach importance to them and would be induced to act on the information in making
23 decisions. Reasonable consumers would have been expected to have relied on the omissions.

24 200. Natera possessed superior knowledge regarding the accuracy and reliability of its NIPT
25 tests, which was not reasonably discoverable by Plaintiffs, Maryland Subclass members, or their treating
26 physicians. Plaintiff Heryla and Maryland Subclass members reasonably relied on Natera's omissions to
27 their detriment, including by paying money for testing they would not have utilized had they been
28 apprised of the true facts.

201. Defendant knew or should have known that its omissions were false and misleading, and intended for consumers to rely on such omissions.

202. Plaintiff Heryla and Maryland Subclass members suffered ascertainable loss as a direct and proximate result of Natera's unfair, abusive, and deceptive trade practices. Had Plaintiff Heryla and Maryland Subclass members known the truth regarding Natera's NIPT test, they would not have purchased a test, or would have paid significantly less for one. Among other injuries, Plaintiff Heryla and Maryland Subclass members overpaid for their NIPT tests and did not receive the value they bargained for.

203. Accordingly, Plaintiff Heryla and Maryland Subclass members are entitled to actual compensatory damages and reasonable attorneys' fees pursuant to Md. Code Com. Law § 13-408.

COUNT IV

Violation of the Illinois Consumer Fraud and Deceptive Business Practices Act (815 Ill. Comp. Stat. § 505/1, *et seq.*)

204. Plaintiffs incorporate and reallege the foregoing allegations of fact.

205. Plaintiff Delaurie brings this claim on behalf of herself and the Illinois Subclass.

206. Plaintiff Delaurie and Illinois Subclass members are "consumers" within the meaning of 815 Ill. Comp. Stat. § 505/1(e).

207. Plaintiff Delaurie, Illinois Subclass members, and Natera are "persons" within the meaning of 815 Ill. Comp. Stat. § 505/1(c).

208. Natera engages in "trade" or "commerce" within the meaning of 815 Ill. Comp. Stat. § 505/1(f).

209. Natera engages in the "sale" of "merchandise" as those terms are defined by 815 Ill. Comp. Stat. § 505/1(b) and (d).

210. Illinois law prohibits "[u]nfair methods of competition and unfair or deceptive acts or practices, including but not limited to the use or employment of any deception fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact . . . in the conduct of any trade or commerce." 815 Ill. Comp. Stat. § 505/2.

211. Natera engaged in unfair acts and practices by developing and selling Panorama NIPT tests that were inaccurate and unreliable to test for a variety of genetic abnormalities. Natera derived a substantial financial benefit from its sale of these tests.

212. Natera engaged in deceptive practices by omitting material information for purposes of inducing consumers to purchase and submit to Natera for prenatal testing services. Natera actively suppressed and failed to disclose material facts concerning the accuracy and reliability of its NIPT test, including:

- (a) knowingly and intentionally concealing from Plaintiffs, Class members, and their physicians the fact that the Panorama test is widely inaccurate for many rare disorders, is highly susceptible to false positives, and cannot be relied on to make critical decisions during a pregnancy;
- (b) failing to disclose that the PPV for rare but serious conditions such as Trisomy 13, Monosomy X, and DiGeorge Syndrome is much lower, sometimes as low as 2-5%;
- (c) failing to reveal that for rare disorders such as DiGeorge syndrome, there is actually an 80% or greater chance a positive result is wrong; and
- (d) failing to disclose the high risk of false positives.

213. Natera omitted such material facts for purposes of inducing consumers to purchase and submit to Natera for prenatal testing services. Natera knowingly sold inaccurate and unreliable NIPT tests, made misleading and deceptive claims regarding its NIPT tests, and failed to disclose the complete truth regarding its NIPT tests to consumers and their treating physicians.

214. Natera's conduct was fraudulent and deceptive because the omissions and incomplete disclosures of fact had the capacity, tendency, and effect of deceiving or misleading reasonable consumers and did, in fact, deceive and mislead reasonable consumers including the Plaintiffs.

215. Reasonable consumers, including Plaintiff Delaurie and the Illinois Subclass, would have found it material to their purchasing decisions that Natera's products (i) were not reasonably accurate or reliable, (ii) have a low positive predictive value, (iii) were not diagnostic tests, and (iv) cannot replace

1 diagnostic tests. Knowledge of these facts would have been a substantial factor in Plaintiff Delaurie's
2 and Illinois Subclass members' decisions to purchase Natera's products.

3 216. Natera owed Plaintiff Delaurie and Illinois Subclass members a duty to disclose these
4 facts because Natera had exclusive and superior knowledge of them; because they would be material to
5 reasonable consumers; and because Natera intended for consumers to rely on the omissions in question.

6 217. Natera could have readily disclosed the entire truth regarding its Panorama NIPT tests to
7 Plaintiff Delaurie and Illinois Subclass members through various sources, including its website, product
8 brochures and marketing materials, and through Plaintiff Delaurie and Illinois Subclass members'
9 physicians and health care providers.

10 218. Defendant's omissions and incomplete disclosures were pervasive and deceived Plaintiff
11 Delaurie and Illinois Subclass members, and have a tendency to deceive the general public regarding the
12 reliability and value of the Panorama NIPT test. The omissions and incomplete disclosures by Natera
13 alleged herein were material in that a reasonable person would attach importance to them and would be
14 induced to act on the information in making decisions. Reasonable consumers would have been
15 expected to have relied on Natera's omissions and incomplete disclosures at issue.

16 219. Natera possessed superior knowledge regarding the accuracy and reliability of its NIPT
17 tests, which was not reasonably discoverable by Plaintiff Delaurie, Illinois Subclass members, or their
18 treating physicians.

19 220. As a direct and proximate result of Natera's deceptive and unfair acts and practices,
20 Plaintiff Delaurie and Illinois Subclass members sustained ascertainable losses in that Plaintiff Delaurie
21 and Illinois Subclass members would not have paid for the Panorama NIPT tests or would have paid
22 significantly less for them but for Natera's omissions of material fact. Among other injuries, Plaintiff
23 Delaurie and Illinois Subclass members overpaid for their NIPT tests and did not receive the value they
24 reasonably expected and bargained for.

25 221. Natera knew or should have known that its omissions and incomplete disclosures of fact
26 were false and misleading, and intended for consumers to rely on them.

222. Accordingly, pursuant to 815 Ill. Comp. Stat. § 505/10a(a), Plaintiff Delaurie and the Illinois Subclass are entitled to compensatory damages, punitive damages under 815 Ill. Comp. Stat. § 505/10a(c), injunctive relief, and reasonable attorneys' fees.

COUNT V

Violation of the Florida Deceptive and Unfair Practices Act (Fla. Stat. §§ 501.201 *et seq.*)

223. Plaintiffs incorporate and reallege the foregoing allegations of fact.

224. Plaintiff Law brings this claim on behalf of herself and the Florida Subclass.

225. Plaintiff Law and Florida Subclass members are "consumers" within the meaning of the Florida Unfair and Deceptive and Unfair Trade Practices Act ("FDUTPA"), Fla. Stat. § 501.203(7).

226. Defendant is engaged in "trade or commerce" within the meaning of Fla. Stat. § 501.203(8).

227. The FDUTPA prohibits "[u]nfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce." Fla. Stat. § 501.204(1). Defendant engaged in unfair and deceptive trade practices that violate the FDUTPA.

228. Natera engaged in unfair acts and practices by developing and selling Panorama NIPT tests that were inaccurate and unreliable to test for a variety of genetic abnormalities. Natera derived a substantial financial benefit from its sale of these tests.

229. Natera engaged in deceptive and unfair practices by omitting material information for purposes of inducing consumers to purchase and submit to Natera for prenatal testing services. Natera actively suppressed and failed to disclose material facts concerning the accuracy and reliability of its NIPT test, including:

- (a) knowingly and intentionally concealing from Plaintiffs, Class members, and their physicians the fact that the Panorama test is widely inaccurate for many rare disorders, is highly susceptible to false positives, and cannot be relied on to make critical decisions during a pregnancy;
- (b) failing to disclose that the PPV for rare but serious conditions such as Trisomy 13, Monosomy X, and DiGeorge Syndrome is much lower, sometimes as low as 2-5%;

- 1 (c) failing to reveal that for rare disorders such as DiGeorge syndrome, there is
2 actually an 80% or greater chance a positive result is wrong; and
3 (d) failing to disclose the high risk of false positives.

4 230. Natera omitted such material facts for purposes of inducing consumers to purchase and
5 submit to Natera for prenatal testing services.

6 231. Natera knew that its NIPT test is inaccurate and unreliable, and that it was thus
7 committing deceptive acts and practices. Plaintiff Law and the Florida Subclass were deceived by
8 Defendant's omissions into believing that the Panorama NIPT tests were highly accurate and reliable to
9 test for a variety of rare genetic conditions, when in reality the tests generate an unreasonably high
10 number of false positive results and cannot be relied upon to make important pregnancy decisions.

11 232. Natera owed Plaintiff Law and Florida Subclass members a duty to disclose these facts
12 because Natera had exclusive and superior knowledge of them; because they would be material to
13 reasonable consumers; and because Natera intended for consumers to rely on the omissions in question.

14 233. Natera could have readily disclosed the truth regarding its Panorama NIPT tests to
15 Plaintiff Law and Florida Subclass members through various sources, including its website, product
16 brochures and marketing materials, and through Plaintiff Law's and Florida Subclass members'
17 physicians and health care providers.

18 234. Reasonable consumers, including Plaintiff Law and the Florida Subclass, would have
19 found it material to their purchasing decisions that Natera's products (i) were not reasonably accurate or
20 reliable, (ii) have a low positive predictive value, (iii) were not diagnostic tests, and (iv) cannot replace
21 diagnostic tests. Knowledge of these facts would have been a substantial factor in Plaintiff Law's and
22 the Florida Subclass's decisions to purchase Natera's products. But Defendant did not disclose these
23 material facts.

24 235. Natera's unfair or deceptive acts or practices were likely to deceive reasonable
25 consumers, including Plaintiff Law and the Florida Subclass, about the true nature of the Panorama
26 NIPT tests that Natera manufactures, advertises, sells, and distributes.

27 236. Plaintiff Law and the Florida Subclass suffered ascertainable loss caused by Natera's
28 material omissions and misleading incomplete disclosures of facts. But for Natera's deceptive and

1 unfair conduct, Plaintiff Law and the Florida Subclass would not have purchased the Panorama NIPT
2 tests.

3 237. As a direct and proximate result of Defendant's FDUTPA violations, Plaintiff Law and
4 the Florida Subclass suffered injury in fact and actual damages.

5 238. Plaintiff Law and the Florida Subclass also seek an order pursuant to Fla. Stat. § 501.211
6 enjoining Defendant's unfair, unlawful, and/or deceptive practices, declaratory relief, attorneys' fees,
7 and any other just and proper relief available under the FDUTPA.

8 **COUNT VI**

9 **Violation of the New Jersey Consumer Fraud Act (N.J.S.A. §§ 56:8-1, *et seq.*)**

10 239. Plaintiffs incorporate and reallege the foregoing allegations of fact.

11 240. Plaintiff Kreynstein brings this claim on behalf of herself and the New Jersey Subclass.

12 241. Plaintiff Kreynstein and members of the New Jersey Subclass are consumers who
13 purchased the Panorama NIPT tests for personal use.

14 242. The New Jersey Consumer Fraud Act ("NJCFA"), N.J.S.A. §§ 56:8-1, *et seq.*, prohibits
15 "[t]he act, use or employment by any person of any unconscionable commercial practice, deception,
16 fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or
17 omission of any material fact with intent that others rely upon such concealment, suppression or
18 omission, in connection with the sale or advertisement of any merchandise or real estate, or with the
19 subsequent performance of such person as aforesaid, whether or not any person has in fact been misled,
20 deceived or damaged thereby, is declared to be an unlawful practice." N.J.S.A. § 56:8-2.

21 243. Natera engaged in unconscionable commercial practices, deception, fraud, and/or false
22 pretense by developing and selling Panorama NIPT tests that were inaccurate and unreliable to test for a
23 variety of genetic abnormalities. Natera derived a substantial financial benefit from its sale of these
24 tests.

25 244. Moreover, Natera also engaged in unconscionable commercial practices, deception,
26 fraud, and/or false pretense by omitting material information for purposes of inducing consumers to
27 purchase and submit to Natera for prenatal testing services. Natera actively suppressed and failed to
28 disclose material facts concerning the accuracy and reliability of its NIPT test, including:

- 1 (a) knowingly and intentionally concealing from Plaintiffs, Class members, and their
- 2 physicians the fact that the Panorama test is widely inaccurate for many rare
- 3 disorders, is highly susceptible to false positives, and cannot be relied on to make
- 4 critical decisions during a pregnancy;
- 5 (b) failing to disclose that the PPV for rare but serious conditions such as Trisomy 13,
- 6 Monosomy X, and DiGeorge Syndrome is much lower, sometimes as low as 2-
- 7 5%;
- 8 (c) failing to reveal that for rare disorders such as DiGeorge syndrome, there is
- 9 actually an 80% or greater chance a positive result is wrong; and
- 10 (d) failing to disclose the high risk of false positives.

11 245. Natera omitted such material facts for purposes of inducing consumers to purchase and
 12 submit to Natera for prenatal testing services. Natera knowingly sold inaccurate and unreliable NIPT
 13 tests, made misleading and deceptive claims regarding its NIPT tests, and failed to disclose the complete
 14 truth regarding its NIPT tests to consumers and their treating physicians.

15 246. Natera's conduct was fraudulent and deceptive because the omissions and incomplete
 16 disclosures of fact had the capacity, tendency and effect of deceiving or misleading reasonable
 17 consumers and did, in fact, deceive and mislead reasonable consumers including the Plaintiffs.

18 247. Defendant's fraudulent omissions were material to Plaintiff Kreynstein and members of
 19 the New Jersey Subclass. When Plaintiff Kreynstein and members of the New Jersey Subclass
 20 purchased their Panorama NIPT tests, they reasonably relied on the natural and legitimate expectation
 21 that the Panorama NIPT tests would accurately tell them whether their pregnancies were at a high risk
 22 for certain serious genetic conditions. Had Defendant disclosed that the Panorama NIPT tests were
 23 unreliable and often inaccurate, Plaintiff Kreynstein and members of the New Jersey Subclass would not
 24 have purchased the Panorama NIPT tests or would have paid less for them.

25 248. Natera could have readily disclosed the truth regarding its Panorama NIPT tests to
 26 Plaintiffs and New Jersey Subclass members through various sources, including its website, product
 27 brochures and marketing materials, and through Plaintiff Kreynstein's and New Jersey Subclass
 28 members' physicians and health care providers.

1 249. Reasonable consumers, including Plaintiff Kreynstein and the New Jersey Subclass,
2 would have found it material to their purchasing decisions that Natera's products (i) were not reasonably
3 accurate or reliable, (ii) have a low positive predictive value, (iii) were not diagnostic tests, and (iv)
4 cannot replace diagnostic tests. Knowledge of these facts would have been a substantial factor in
5 Plaintiff Kreynstein's and the New Jersey Subclass's decisions to purchase Natera's products. But
6 Defendant did not disclose these material facts.

7 250. Natera knowingly failed to disclose the truth regarding Panorama NIPT tests at the time
8 of sale and at all relevant times thereafter.

9 251. Natera owed Plaintiff Kreynstein and New Jersey Subclass members a duty to disclose
10 these facts because Natera had exclusive and superior knowledge of them; because they would be
11 material to reasonable consumers; and because Natera intended for consumers to rely on the omissions
12 in question.

13 252. As a direct and proximate result of Natera's wrongful conduct in violation of the NJCFA,
14 Plaintiff Kreynstein and members of the New Jersey Subclass have suffered and continue to suffer
15 ascertainable loss because, had Plaintiff Kreynstein and members of the New Jersey Subclass known
16 that the Panorama NIPT tests were unreliable and often inaccurate at the time of purchase, they would
17 not have bought the Panorama NIPT tests or would have paid much less for them. Thus, Plaintiff
18 Kreynstein and members of the New Jersey Subclass paid a price premium on account of Defendant's
19 failure to disclose material facts.

20 253. As a result of Defendant's unconscionable, fraudulent, and deceptive conduct, Plaintiff
21 Kreynstein and members of the New Jersey Subclass are entitled to actual damages, treble damages,
22 costs, attorneys' fees, and other damages to be determined at trial. *See* N.J.S.A. § 56:8-19.

23 254. Plaintiff Kreynstein and members of the New Jersey Subclass also seek an order
24 enjoining Defendant's unlawful, fraudulent and/or deceptive practices, and any other just and proper
25 declaratory or equitable relief available under the NJCFA. *See* N.J.S.A. § 56:8-19.

COUNT VII**Violation of New York's General Business Law § 349**

255. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

256. Plaintiff Stephens brings this claim individually and on behalf of the members of the proposed New York Subclass against Defendant.

257. New York's Gen. Bus. Law ("GBL") § 349(a) prohibits "[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state."

258. GBL Section 349 requires a plaintiff to show that (1) the defendant's deceptive acts were directed at consumers, (2) the acts are misleading in a material way, and (3) the plaintiff has been injured by consequence of them. Section 349 does not require proof of reliance or proof that the defendant intended to mislead consumers.

259. Defendant committed deceptive acts and practices by failing to disclose material facts regarding the Panorama NIPT tests' accuracy and reliability, as described above.

260. These deceptive acts and practices were directed at consumers. These acts and practices, moreover, were misleading in a material way because they fundamentally misrepresent that the Panorama NIPT tests were capable of producing reliable, accurate, and trustworthy screening results. Further, in consequence of Defendant's omissions, Plaintiff Stephens and members of the New York Subclass suffered economic injury because they would not have purchased the Panorama NIPT test, or would have paid substantially less for it, but for Defendant's materially misleading omissions concerning the test's accuracy and reliability.

261. On behalf of herself and the other members of the New York Subclass, Plaintiff Stephens seeks to recover actual damages or fifty dollars, whichever is greater, three times actual damages, and reasonable attorneys' fees.

COUNT VIII**Violation of New York's General Business Law § 350**

262. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

1 263. Plaintiff Stephens brings this claim individually and on behalf of the members of the
2 proposed Subclass against Defendant.

3 264. New York’s GBL § 350 prohibits “[f]alse advertising in the conduct of any business,
4 trade or commerce or in the furnishing of any service in this state.” The statute defines false advertising
5 as: advertising, including labeling, of a commodity, or of the kind, character, terms or conditions of any
6 employment opportunity if such advertising is misleading in a material respect. In determining whether
7 any advertising is misleading, there shall be taken into account (among other things) not only
8 representations made by statement, word, design, device, sound or any combination thereof, but also the
9 extent to which the advertising fails to reveal facts material in the light of such representations with
10 respect to the commodity or employment to which the advertising relates under the conditions
11 prescribed in said advertisement, or under such conditions as are customary or usual.

12 265. GBL Section 350 requires a plaintiff to show that (1) the defendant’s deceptive acts were
13 directed at consumers, (2) the acts are misleading in a material way, and (3) the plaintiff has been
14 injured by consequence of them. Section 350 does not require proof of reliance or proof that the
15 defendant intended to mislead consumers.

16 266. Defendant engaged in consumer-directed conduct that is deceptive or misleading in a
17 material way and which constitutes false advertising in violation of GBL § 350 by misrepresenting the
18 qualities and characteristics of the Panorama NIPT test, and failing to disclose the test’s inaccuracy and
19 unreliability.

20 267. The foregoing advertising was directed at consumers and was likely to mislead a
21 reasonable consumer acting reasonably under the circumstances.

22 268. These omissions have resulted in consumer injury or harm to the public interest.

23 269. Defendant alone possessed the knowledge that the Panorama test was not capable of
24 producing reliable, accurate, and trustworthy results.

25 270. As a result of Defendant’s omissions, Plaintiff Stephens and members of the New York
26 Subclass suffered economic injury because they would not have purchased the Panorama NIPT, or
27 would have paid substantially less for it, but for Defendant’s omissions concerning the test’s accuracy
28 and reliability.

1 Illinois Subclass members would require that their NIPT tests provide reliable and accurate information
 2 regarding genetic abnormalities that may affect their pregnancy and the well-being of their baby. Natera
 3 delivered its NIPT tests to Plaintiff Delaurie and Illinois Subclass members understanding the need to
 4 meet these requirements.

5 293. Plaintiff Delaurie was excused from providing Natera with notice and opportunity to cure
 6 the breach because it would have been futile. Natera has long been aware that the inaccuracy and
 7 unreliability of its Panorama NIPT tests render the tests unsuitable for identifying rare abnormalities
 8 during pregnancies and making decisions regarding medical treatment. Plaintiff had no reason to believe
 9 Natera could have improved the accuracy and reliability of these tests, had she contacted Natera.

10 294. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiff
 11 Delaurie and Illinois Subclass members have been damaged in an amount to be proven at trial.

12 **COUNT XII**

13 **Breach of Implied Warranty (Maryland law)**

14 295. Plaintiffs incorporate and reallege the foregoing allegations of facts.

15 296. Plaintiff Heryla brings this claim on behalf of herself and the Maryland Subclass under
 16 Maryland law.

17 297. As the manufacturer, designer, marketer, and/or seller of NIPT tests, by operation of law,
 18 Natera warranted that its Panorama NIPT tests would, among other things, pass without objection in the
 19 trade and are fit for the ordinary purposes for which such goods are used.

20 298. At all relevant times, Natera's NIPT tests were not in merchantable condition or fit for
 21 the ordinary purpose for which prenatal tests are used. The lack of accuracy and reliability render the
 22 tests unsuitable for identifying rare abnormalities during pregnancies and making decisions regarding
 23 medical treatment, as they frequently produce false positives. The PPV for more rare genetic conditions
 24 for which Panorama screens is as low as 2-5%.

25 299. Plaintiff Heryla, Maryland Subclass members, and their doctors relied on Natera's claims
 26 regarding the accuracy and reliability of its NIPT tests in purchasing the tests and making decisions
 27 regarding their pregnancy and treatment.
 28

1 medical treatment, as they frequently produce false positives. The PPV for more rare genetic conditions
2 for which Panorama screens is as low as 2-5%.

3 307. Plaintiff Kreynstein, New Jersey Subclass members, and their doctors relied on Natera's
4 claims regarding the accuracy and reliability of its NIPT tests in purchasing the tests and making
5 decisions regarding their pregnancy and treatment.

6 308. Plaintiff Kreynstein and New Jersey Subclass members are the intended third-party
7 beneficiaries of agreements between Natera and their physicians and health insurers. The agreements
8 between Natera and Plaintiff Kreynstein's and New Jersey Subclass members' physicians and health
9 insurers to use Natera's NIPT test for genetic testing were designed and intended for the benefit of
10 Plaintiff Kreynstein and New Jersey Subclass members to make health care decisions. Natera also
11 understood that Plaintiff Kreynstein and New Jersey Subclass members would require that their NIPT
12 tests provide reliable and accurate information regarding genetic abnormalities that may affect their
13 pregnancy and the well-being of their baby. Natera delivered its NIPT tests to Plaintiff Kreynstein and
14 New Jersey Subclass members understanding the need to meet these requirements.

15 309. Plaintiff Kreynstein was excused from providing Natera with notice and opportunity to
16 cure the breach because it would have been futile. Natera has long been aware that the inaccuracy and
17 unreliability of its Panorama NIPT tests render the tests unsuitable for identifying rare abnormalities
18 during pregnancies and making decisions regarding medical treatment. Plaintiff had no reason to believe
19 Natera could have improved the accuracy and reliability of these tests, had she contacted Natera.

20 310. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiff
21 Kreynstein and New Jersey Subclass members have been damaged in an amount to be proven at trial.

22 **COUNT XIV**

23 **Breach of Implied Warranty (New York law)**

24 311. Plaintiffs incorporate and reallege the foregoing allegations of facts.

25 312. Plaintiff Stephens brings this claim on behalf of herself and the New York Subclass under
26 New York law.
27
28

1 313. As the manufacturer, designer, marketer, and/or seller of NIPT tests, by operation of law,
2 Natera warranted that its Panorama NIPT tests would, among other things, pass without objection in the
3 trade and are fit for the ordinary purposes for which such goods are used.

4 314. At all relevant times, Natera's NIPT tests were not in merchantable condition or fit for
5 the ordinary purpose for which prenatal tests are used. The lack of accuracy and reliability render the
6 tests unsuitable for identifying rare abnormalities during pregnancies and making decisions regarding
7 medical treatment, as they frequently produce false positives. The PPV for more rare genetic conditions
8 for which Panorama screens is as low as 2-5%.

9 315. Plaintiff Stephens, New York Subclass members, and their doctors relied on Natera's
10 claims regarding the accuracy and reliability of its NIPT tests in purchasing the tests and making
11 decisions regarding their pregnancy and treatment.

12 316. Plaintiff Stephens and New York Subclass members are the intended third-party
13 beneficiaries of agreements between Natera and their physicians and health insurers. The agreements
14 between Natera and Plaintiff Stephens's and New York Subclass members' physicians and health
15 insurers to use Natera's NIPT test for genetic testing were designed and intended for the benefit of
16 Plaintiff Stephens and New York Subclass members to make health care decisions. Natera also
17 understood that Plaintiff Stephens and New York Subclass members would require that their NIPT tests
18 provide reliable and accurate information regarding genetic abnormalities that may affect their
19 pregnancy and the well-being of their baby. Natera delivered its NIPT tests to Plaintiff Stephens and
20 New York Subclass members understanding the need to meet these requirements.

21 317. Plaintiff Stephens was excused from providing Natera with notice and opportunity to cure
22 the breach because it would have been futile. Natera has long been aware that the inaccuracy and
23 unreliability of its Panorama NIPT tests render the tests unsuitable for identifying rare abnormalities
24 during pregnancies and making decisions regarding medical treatment. Plaintiff had no reason to believe
25 Natera could have improved the accuracy and reliability of these tests, had she contacted Natera.

26 318. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiff
27 Stephens and New York Subclass members have been damaged in an amount to be proven at trial.
28

COUNT XV**Breach of Implied Warranty (Ohio law)**

319. Plaintiffs incorporate and reallege the foregoing allegations of facts.

320. Plaintiff Davis brings this claim on behalf of herself and the Ohio Subclass under Ohio law.

321. As the manufacturer, designer, marketer, and/or seller of NIPT tests, by operation of law, Natera warranted that its Panorama NIPT tests would, among other things, pass without objection in the trade and are fit for the ordinary purposes for which such goods are used.

322. At all relevant times, Natera's NIPT tests were not in merchantable condition or fit for the ordinary purpose for which prenatal tests are used. The lack of accuracy and reliability render the tests unsuitable for identifying rare abnormalities during pregnancies and making decisions regarding medical treatment, as they frequently produce false positives. The PPV for more rare genetic conditions for which Panorama screens is as low as 2-5%.

323. Plaintiff Davis, Ohio Subclass members, and their doctors relied on Natera's claims regarding the accuracy and reliability of its NIPT tests in purchasing the tests and making decisions regarding their pregnancy and treatment.

324. Plaintiff Davis and Ohio Subclass members are the intended third-party beneficiaries of agreements between Natera and their physicians and health insurers. The agreements between Natera and Plaintiff Davis's and Ohio Subclass members' physicians and health insurers to use Natera's NIPT test for genetic testing were designed and intended for the benefit of Plaintiff Davis and Ohio Subclass members to make health care decisions. Natera also understood that Plaintiff Davis and Ohio Subclass members would require that their NIPT tests provide reliable and accurate information regarding genetic abnormalities that may affect their pregnancy and the well-being of their baby. Natera delivered its NIPT tests to Plaintiff Davis and Ohio Subclass members understanding the need to meet these requirements.

325. Plaintiff Davis was excused from providing Natera with notice and opportunity to cure the breach because it would have been futile. Natera has long been aware that the inaccuracy and unreliability of its Panorama NIPT tests render the tests unsuitable for identifying rare abnormalities

1 during pregnancies and making decisions regarding medical treatment. Plaintiff had no reason to believe
 2 Natera could have improved the accuracy and reliability of these tests, had she contacted Natera.

3 326. As a direct and proximate result of Defendant's breach of implied warranties, Plaintiff
 4 Davis and Ohio Subclass members have been damaged in an amount to be proven at trial.

5 **COUNT XVI**

6 **Unjust Enrichment (California law)**

7 327. Plaintiffs incorporate and reallege the foregoing allegations of fact.

8 328. This equitable count is pled in the alternative to Plaintiffs' claims at law.

9 329. Plaintiffs bring this claim on behalf of themselves and the Class and state Subclasses
 10 under California law.

11 330. Plaintiffs and Class members lack an adequate remedy at law.

12 331. As the intended and expected result of its conscious wrongdoing, Natera has profited and
 13 benefitted from Plaintiffs and Class members' purchases of Panorama NIPT tests.

14 332. Natera has voluntarily accepted and retained these profits and benefits, knowing that, as a
 15 result of its misconduct alleged herein, Plaintiffs and the Class were not receiving accurate test results an
 16 ordinary consumer would expect. Plaintiffs and Class members reasonably expected that when they
 17 purchased a Panorama NIPT test, they would be able to rely on the results to make potentially life-
 18 altering decisions regarding their pregnancy and their course of treatment.

19 333. Natera has been unjustly enriched by its deceptive, wrongful, and unscrupulous conduct
 20 and by its withholding of benefits and unearned monies from Plaintiffs and the Class rightfully
 21 belonging to them. Equity and good conscience militate against permitting Natera to retain these profits
 22 and benefits from its wrongful conduct. They should accordingly be disgorged or placed in a
 23 constructive trust so that Plaintiffs and Class members can obtain restitution.

24 **COUNT XVII**

25 **Unjust Enrichment (Florida law)**

26 334. Plaintiffs incorporate and reallege the foregoing allegations of fact.

27 335. This equitable count is pled in the alternative to Plaintiffs' claims at law.
 28

1 members reasonably expected that when they purchased a Panorama NIPT test, they would be able to
 2 rely on the results to make potentially life-altering decisions regarding their pregnancy and their course
 3 of treatment.

4 347. Natera has been unjustly enriched by its deceptive, wrongful, and unscrupulous conduct
 5 and by its withholding of benefits and unearned monies from Plaintiff Delaurie and the Illinois Subclass
 6 rightfully belonging to them. Equity and good conscience militate against permitting Natera to retain
 7 these profits and benefits from its wrongful conduct. They should accordingly be disgorged or placed in
 8 a constructive trust so that Plaintiff Delaurie and Illinois Subclass members can obtain restitution.

9 **COUNT XIX**

10 **Unjust Enrichment (Maryland law)**

11 348. Plaintiffs incorporate and reallege the foregoing allegations of fact.

12 349. This equitable count is pled in the alternative to Plaintiffs' claims at law.

13 350. Plaintiff Heryla brings this claim on behalf of herself and the Maryland Subclass under
 14 Maryland law.

15 351. Plaintiff Heryla and Maryland Subclass members lack an adequate remedy at law.

16 352. As the intended and expected result of its conscious wrongdoing, Natera has profited and
 17 benefitted from Plaintiff Heryla and Maryland Subclass members' purchases of Panorama NIPT tests.

18 353. Natera has voluntarily accepted and retained these profits and benefits, knowing that, as a
 19 result of its misconduct alleged herein, Plaintiff Heryla and the Maryland Subclass were not receiving
 20 accurate test results an ordinary consumer would expect. Plaintiff Heryla and Maryland Subclass
 21 members reasonably expected that when they purchased a Panorama NIPT test, they would be able to
 22 rely on the results to make potentially life-altering decisions regarding their pregnancy and their course
 23 of treatment.

24 354. Natera has been unjustly enriched by its deceptive, wrongful, and unscrupulous conduct
 25 and by its withholding of benefits and unearned monies from Plaintiff Heryla and the Maryland Subclass
 26 rightfully belonging to them. Equity and good conscience militate against permitting Natera to retain
 27 these profits and benefits from its wrongful conduct. They should accordingly be disgorged or placed in
 28 a constructive trust so that Plaintiff Heryla and Maryland Subclass members can obtain restitution.

COUNT XX

Unjust Enrichment (New Jersey law)

355. Plaintiffs incorporate and reallege the foregoing allegations of fact.

356. This equitable count is pled in the alternative to Plaintiffs' claims at law.

357. Plaintiff Kreynstein brings this claim on behalf of herself and the New Jersey Subclass under New Jersey law.

358. Plaintiff Kreynstein and New Jersey Subclass members lack an adequate remedy at law.

359. As the intended and expected result of its conscious wrongdoing, Natera has profited and benefitted from Plaintiff Kreynstein and New Jersey Subclass members' purchases of Panorama NIPT tests.

360. Natera has voluntarily accepted and retained these profits and benefits, knowing that, as a result of its misconduct alleged herein, Plaintiff Kreynstein and the New Jersey Subclass were not receiving accurate test results an ordinary consumer would expect. Plaintiff Kreynstein and New Jersey Subclass members reasonably expected that when they purchased a Panorama NIPT test, they would be able to rely on the results to make potentially life-altering decisions regarding their pregnancy and their course of treatment.

361. Natera has been unjustly enriched by its deceptive, wrongful, and unscrupulous conduct and by its withholding of benefits and unearned monies from Plaintiff Kreynstein and the New Jersey Subclass rightfully belonging to them. Equity and good conscience militate against permitting Natera to retain these profits and benefits from its wrongful conduct. They should accordingly be disgorged or placed in a constructive trust so that Plaintiff Kreynstein and New Jersey Subclass members can obtain restitution.

COUNT XXI

Unjust Enrichment (New York law)

362. Plaintiffs incorporate and reallege the foregoing allegations of fact.

363. This equitable count is pled in the alternative to Plaintiffs' claims at law.

364. Plaintiff Stephens brings this claim on behalf of herself and the New York Subclass under New York law.

1 results to make potentially life-altering decisions regarding their pregnancy and their course of
2 treatment.

3
4 375. Natera has been unjustly enriched by its deceptive, wrongful, and unscrupulous conduct
5 and by its withholding of benefits and unearned monies from Plaintiff Davis and the Ohio Subclass
6 rightfully belonging to them. Equity and good conscience militate against permitting Natera to retain
7 these profits and benefits from its wrongful conduct. They should accordingly be disgorged or placed in
8 a constructive trust so that Plaintiff Davis and Ohio Subclass members can obtain restitution.

9 **VIII. PRAYER FOR RELIEF**

10 WHEREFORE, Plaintiffs, on behalf of themselves and the members of the Class, respectfully
11 request that this Court:

- 12 (a) Determine that the claims alleged herein may be maintained as a class action under Rule
13 23 of the Federal Rules of Civil Procedure, and issue an order certifying the Class and
14 Subclasses as defined above and appoint Plaintiffs as representative of the Class and
15 Subclasses and their counsel as Class Counsel;
- 16 (b) Award all actual, general, special, incidental, statutory, punitive, and consequential
17 damages to which Plaintiffs and Class members are entitled;
- 18 (c) Award pre-judgment and post-judgment interest on such monetary relief;
- 19 (d) Grant appropriate injunctive and/or declaratory relief, including, without limitation, an
20 order enjoining Natera from continuing the wrongful, deceptive, and unfair business
21 practices described in this Complaint;
- 22 (e) Award reasonable attorneys' fees and costs as provided by law; and
- 23 (f) Grant such further and other relief that this Court deems appropriate.

24 **IX. DEMAND FOR JURY TRIAL**

25 Plaintiffs hereby demand a trial by jury for all claims so triable.

26 Dated: April 27, 2023

By: /s/ L. Timothy Fisher
L. Timothy Fisher

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Dated: April 27, 2023

By: /s/ Dena C. Sharp

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